Virginia Administrative Code
Title 12. Health
Agency 5. Department of Health
Chapter 481. Virginia Radiation Protection Regulations

12VAC5-481-10. Definitions.

Part I. General Provisions

The following words and terms as used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"A_1" means the maximum activity of special form radioactive material permitted in a Type A package. This value is listed in Table 1 of 12VAC5-481-3770 F.

"A_2" means the maximum activity of radioactive material, other than special form radioactive material, LSA, and SCO material, permitted in a Type A package. This value is listed in Table 1 of 12VAC5-481-3770 F.

"Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

"Absorbed dose rate" means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

"Accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one MeV. For purposes of this definition, "particle accelerator" is an equivalent term.

"Accelerator-produced material" means any material made radioactive by a particle accelerator.

"Access control" means a system for allowing only approved individuals to have unescorted access to the security zone and for ensuring that all other individuals are subject to escorted access.

"Accessible surface" means the external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer. It also means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

"Act" means §§ 32.1-227 through 32.1-238 of the Code of Virginia.

"Active maintenance" means any significant activity needed during the period of institutional control to maintain a reasonable assurance that the performance objectives in 12VAC5-481-2490 and 12VAC5-481-2500 are met. Such active maintenance includes ongoing activities such as the pumping and treatment of water from a disposal unit or one-time measures such as replacement of a disposal unit cover. Active maintenance does not include custodial

activities such as repair of fencing, repair or replacement of monitoring equipment, revegetation, minor additions to soil cover, minor repair of disposal unit covers, and general disposal site upkeep such as mowing grass.

"Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

"Acute" means a single radiation dose or chemical exposure event or multiple radiation dose or chemical exposure events occurring within a short time (24 hours or less).

"Address of use" means the building or buildings that are identified on the license and where radioactive material may be produced, prepared, received, used, or stored.

"Adult" means an individual 18 or more years of age.

"Agency" means the Radiological Health Program of the Virginia Department of Health.

"Aggregated" means accessible by the breach of a single physical barrier that would allow access to radioactive material in any form, including any devices that contain the radioactive material, when the total activity equals or exceeds a Category 2 quantity of radioactive material as listed in 12VAC5-481-451 .

"Agreement state" means any state with which the NRC or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended (42 USC § 2021(b)).

"Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

"Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials composed wholly or partly of licensed material exist in concentrations:

1. In excess of the derived air concentrations (DACs) specified in Appendix B to 10 CFR Part 20; or

2. To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6% of the annual limit on intake (ALI) or 12 DAC hours.

"Air kerma" or "K" means kerma in air (see definition of "kerma").

"Air kerma rate" or "AKR" means the air kerma per unit time.

"Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

"Alert" means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons off site.

"Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same

attenuation, under specified conditions, as the material in question. The nominal chemical composition of type 100 aluminum is 99.00% minimum aluminum, 0.12% copper.

"Analytical x-ray equipment" means equipment used for x-ray diffraction or fluorescence analysis.

"Analytical x-ray system" means a group of components utilizing x-rays or gamma-rays to determine the elemental composition or to examine the microstructure of materials.

"Annual limit on intake" or "ALI" means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Tables 1 and 2 in Appendix B to 10 CFR Part 20.

"Annual refresher safety training" means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review shall include, as a minimum, any results of internal inspections, new procedures or equipment, new or revised regulations, and accidents or errors that have been observed. The review shall also provide opportunities for employees to ask safety questions.

"Annually" means at intervals not to exceed one year.

"ANSI" means the American National Standards Institute.

"Approved individual" means an individual whom the licensee has determined to be trustworthy and reliable for unescorted access in accordance with 12VAC5-481-451 and has completed the training required in 12VAC5-481-451 .

"Area of use" means a portion of a physical structure that has been set aside for the purpose of producing, preparing, receiving, using, or storing radioactive material.

"Articulated joint" means a joint between two separate sections of a tabletop that provides the capacity for one of the sections to pivot on the line segment along which the sections join.

"As low as is reasonably achievable" or "ALARA" means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these regulations as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

"Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of

an x-ray system or his employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

"Assigned protection factor" or "APF" means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

"Associated equipment" means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drive, guide, or come in contact with the source.

"Atmosphere-supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

"Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation. The nominal chemical composition of type 100 aluminum is 99.00% minimum aluminum, 0.12% copper.

"Authorized medical physicist" means an individual who:

1. Meets the requirements in 12VAC5-481-1760 and 12VAC5-481-1790; or

2. Is identified as an authorized medical physicist or teletherapy physicist on:

    a. A specific medical use license issued by the NRC or another agreement state;

    b. A medical use permit issued by an NRC master material licensee;

    c. A permit issued by an NRC or another agreement state broad scope medical use licensee; or

    d. A permit issued by an NRC master material license broad scope medical use permittee.

"Authorized nuclear pharmacist" means a pharmacist who:

1. Meets the requirements in 12VAC5-481-1770 and 12VAC5-481-1790;

2. Is identified as an authorized nuclear pharmacist on:

    a. A specific license issued by the NRC or another agreement state that authorizes medical use or the practice of nuclear pharmacy;

    b. A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;

    c. A permit issued by an NRC or another agreement state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

    d. A permit issued by an NRC master material license broad scope medical use

permittee that authorizes medical use or the practice of nuclear pharmacy;

3. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

4. Is designated as an authorized nuclear pharmacist in accordance with 12VAC5-481-440 I 2.

"Authorized user" means a practitioner of the healing arts who:

1. Meets the requirements in 12VAC5-481-1790 and any of the following:

a. 12VAC5-481-1910 ;

b. 12VAC5-481-1940 ;

c. 12VAC5-481-1980 ;

d. 12VAC5-481-1990 ;

e. 12VAC5-481-2000 ;

f. 12VAC5-481-2018 ;

g. 12VAC5-481-2030;

h. 12VAC5-481-2040 A; or

2. Is identified as an authorized user on:

a. A specific license issued by the NRC or another agreement state that authorizes medical use;

b. A permit issued by an NRC master material licensee that authorizes medical use;

c. A permit issued by an NRC or another agreement state broad scope medical use licensee that authorizes medical use; or

d. A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use.

"Automatic exposure control" or "AEC" means a device that automatically controls one or more technique factors in order to obtain, at a preselected location, a required quantity of radiation (includes devices such as phototimers and ion chambers).

"Background investigation" means the investigation conducted by a licensee or applicant to support the determination of trustworthiness and reliability.

"Background radiation" means radiation from cosmic sources, naturally occurring radioactive materials, that have not been technologically enhanced, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices, or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee or registrant. "Background radiation" does not include sources of radiation from

radioactive materials regulated by the agency.

"Barrier" (See "Protective barrier").

"Beam axis" means a line from the source through the centers of the x-ray fields.

"Beam-limiting device" means a device that provides a means to restrict the dimensions of the x-ray field or useful beam.

"Beam monitoring system" means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

"Beam scattering foil" means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

"Becquerel" or "Bq" means the SI unit of activity. One becquerel is equal to one disintegration or transformation per second (dps or tps).

"Beneficial attribute" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, the radioactivity of the product necessary to the use of the product.

"Beneficial to the product" (See "Beneficial attribute").

"Bent beam linear accelerator" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

"Bioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in-vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these regulations, "radiobioassay" is an equivalent term.

"Board" means the State Board of Health.

"Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

"Buffer zone" means a portion of the disposal site that is controlled by the licensee and that lies under the disposal units and between the disposal units and the boundary of the site.

"Byproduct material" means:

1. Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

2. The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct

material" within this definition;

3. a. Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

b. Any material that:

(1) Has been made radioactive by use of a particle accelerator; and

(2) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

4. Any discrete source of naturally occurring radioactive material, other than source material, that:

a. The NRC, in consultation with the Administrator of the U.S. Environmental Protection Agency, the U.S. Secretary of Energy, the U.S. Secretary of Homeland Security, and the head of any other appropriate federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

b. Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

"C-arm fluoroscope" means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

"Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet so shielded that every location on the exterior meets the dose limits for individual members of the public as specified in 12VAC5-481-720 .

"Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. The cabinet x-ray system is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment that may temporarily or occasionally incorporate portable shielding, is not considered a cabinet x-ray system.

"Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. The method observed by the licensee or registrant for determining calendar quarters shall only be changed at the beginning of a year.

"Calibration" means the determination of (i) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument or (ii) the strength of a source of radiation relative to a standard.

"Camera" (See "Radiographic exposure device").

"Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

"Cassette holder" means a device, other than a spot-film device, that supports or fixes the position of an x-ray film (imaging) cassette during an x-ray exposure.

"Category 1 quantities of radioactive material" or "Category 1" means a quantity of radioactive material meeting or exceeding the Category 1 threshold in Table 1 of 12VAC5-481-451 . This is determined by calculating the ratio of the total activity of each radionuclide to the Category 1 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a Category 1 quantity. Category 1 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

"Category 2 quantities of radioactive material" or "Category 2" means a quantity of radioactive material meeting or exceeding the Category 2 threshold but less than the Category 1 threshold in Table 1 of 12VAC5-481-451 . This is determined by calculating the ratio of the total activity of each radionuclide to the Category 2 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a Category 2 quantity. Category 2 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

"Certifiable cabinet x-ray system" means an existing uncertified x-ray system that has been modified to meet the certification requirements specified in 21 CFR 1020.40.

"Certificate holder" means a person who has been issued a certificate of compliance or other package approval by the NRC.

"Certificate of compliance" or "CoC" means the certificate issued by the NRC that approves the design of a package for the transportation of radioactive material.

"Certified cabinet x-ray system" means an x-ray system that has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

"Certified components" means components of x-ray systems that are subject to regulations promulgated under P.L. 90-602, the Radiation Control for Health and Safety Act of 1968 of the Food and Drug Administration.

"Certifying entity" means an independent certifying organization meeting the agency's requirements for documenting applicant's training in topics set forth in 12VAC5-481-1320 or equivalent state or NRC regulations.

"CFR" means Code of Federal Regulations.

"Chelating agent" means amine polycarboxylic acids, hydroxycarboxylic acids, gluconic acid, and polycarboxylic acids.

"Chemical description" means a description of the principal chemical characteristics of a low-level radioactive waste.

"Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days; for Class W, Weeks, from 10 to 100 days; and for Class Y, Years, of greater than 100 days. For purposes of these regulations, "lung class" and "inhalation class" are equivalent terms.

"Closed transport vehicle" means a transport vehicle equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized persons to the cargo space containing the radioactive material. The enclosure may be either temporary or permanent but shall limit access from top, sides, and ends. In the case of packaged materials, it may be of the "see-through" type.

"cm" means centimeters.

"Coefficient of variation or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left[\frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n-1} \right]^{1/2}$$

where:

s = Standard deviation of the observed values;

X = Mean value of observations in sample;

$x_i = i_{th}$ observation in sample;

n = Number of observations in sample.

"Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

"Collimator" means a device used to limit the size, shape, and direction of the primary radiation beam. For industrial radiography it means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

"Commencement of construction" means taking any action defined as "construction" or any other activity at the site of a facility subject to the regulations in this chapter that has a reasonable nexus to radiological health and safety.

"Committed dose equivalent" or "$H_{T,50}$" means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

"Committed effective dose equivalent" or "$H_{E,50}$" means the sum of the products of the weighting factors (w_T) applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = (w_T H_{T,50})$).

"Computed tomography" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

"Computed tomography dose index" means the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$\overline{CTDI} = \frac{1}{n\,T}\int_{-7T}^{+7T} D(z)dz$$

where:

z = Position along a line perpendicular to the tomographic plane;

D(z) = Dose at position z;

T = Nominal tomographic section thickness;

n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z = 0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

"Computer-readable medium" means that the regulatory agency's computer can transfer the information from the medium into its memory.

"Consignee" means the designated receiver of the shipment of low-level radioactive waste.

"Consignment" means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

"Consortium" means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a federal facility or a medical facility.

"Constraint" means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

"Constraint" or "dose constraint" means a value above which specified licensee actions are

required.

"Construction" means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to this chapter. The term "construction" does not include:

1. Changes for temporary use of the land for public recreational purposes;

2. Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

3. Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

4. Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this chapter;

5. Excavation;

6. Erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

7. Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);

8. Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or

9. Taking any other action that has no reasonable nexus to radiological health and safety.

"Contact therapy system" means a therapeutic radiation machine with a short target to skin distance (TSD), usually less than five centimeters.

"Contrast scale" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$\overline{CS} = \frac{\mu_x - \mu_w}{\overline{CTN_x} - \overline{CTN_w}}$$

where:

μ_x = Linear attenuation coefficient of the material of interest;
μ_w = Linear attenuation coefficient of water;
$\overline{CTN}_x$ = of the material of interest;

$\overline{CTN}_W$ = of water.

"Control cable" or "drive" means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

"Control drive mechanism" means a device that enables the source assembly to be moved into and out of the exposure device.

"Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

"Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

"Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

"Conventional simulator" means any x-ray system designed to reproduce the geometric conditions of the radiation therapy equipment.

"Conveyance" means:

1. For transport by public highway or rail any transport vehicle or large freight container;

2. For transport by water any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and

3. For transport by any aircraft.

"Cooling curve" means the graphical relationship between heat units stored and cooling time.

"Cradle" means either:

1. A removable device that supports and may restrain a patient above an x-ray table; or

2. A device:

    a. Whose patient support structure is interposed between the patient and the image receptor during normal use;

    b. Which is equipped with means for patient restraint; and

    c. Which is capable of rotation about its long (longitudinal) axis.

"Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

"Criticality safety index" or "CSI" means the dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages containing fissile material during transportation. Determination of the criticality safety index is described in Part XIII (

12VAC5-481-2950 et seq.).

"CS" (See "Contrast scale").

"CT" (See "Computed tomography").

"CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in these regulations.

"CTDI" (See "Computed tomography dose index").

"CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

"CTN" (See "CT number").

"CT number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

$$\overline{CTN} = \frac{k\,(\mu_x - \mu_w)}{\mu_w}$$

where:

k = A constant, a normal value of 1,000 when the Hounsfield scale of CTN is used;

μ_x = Linear attenuation coefficient of the material of interest;

μ_w = Linear attenuation coefficient of water.

"Cumulative air kerma" means the total air kerma accrued from the beginning of an examination or procedure and includes all contribution from fluoroscopic and radiographic irradiation.

"Curie" is a unit of quantity of activity. One curie (Ci) is that quantity of radioactive material that decays at the rate of 3.7E+10 disintegrations or transformations per second (dps or tps).

"Custodial agency" means an agency of the government designated to act on behalf of the government owner of the disposal site.

"Declared pregnant woman" means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

"Decommission" means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the license or release of the property under restricted conditions and termination of the license.

"Decontamination facility" means a facility operating under a commission or agreement state

license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for purposes of this chapter, is not considered to be a consignee for LLW shipments.

"Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

"Deep dose equivalent" or "$H_{d,}$" which applies to external whole body exposure, means the dose equivalent at a tissue depth of one centimeter (1000 mg/cm^2).

"Demand respirator" means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

"Department of Energy" means the Department of Energy established by P.L. 95-91, August 4, 1977, 91 Stat. 565, 42 USC § 7101 et seq., to the extent that the Department exercises functions formerly vested in the Atomic Energy Commission, its Chairman, members, officers and components and transferred to the Energy Research and Development Administration and to the Administrator thereof pursuant to §§ 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (P.L. 93-438, October 11, 1974, 88 Stat. 1233 at 1237, 42 USC § 5814, effective January 19, 1975) and retransferred to the U.S. Secretary of Energy pursuant to § 301(a) of the Department of Energy Organization Act (P.L. 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 USC § 7151, effective October 1, 1977).

"Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percentage of the total uranium present. Depleted uranium does not include special nuclear material.

"Derived air concentration" or "DAC" means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these regulations, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Appendix B to 10 CFR Part 20.

"Derived air concentration-hour" or "DAC hour" means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

"Detector" (See "Radiation detector").

"Deuterium" means, for the purposes of Part XIII (12VAC5-481-2950 et seq.) of this chapter, deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.

"Diagnostic clinical procedures manual" means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures, where each diagnostic clinical procedure has been

approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

"Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

"Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

"Direct scattered radiation" means that scattered radiation that has been deviated in direction only by materials irradiated by the useful beam (See "Scattered radiation").

"Discrete source" means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

"Disposable respirator" means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator and a disposable escape-only self-contained breathing apparatus (SCBA).

"Disposal" means the isolation of wastes from the biosphere inhabited by man and his food chains by emplacement in a land disposal facility.

"Disposal container" means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see "high integrity container"). Note that for some shipments, the disposal container may be the transport package.

"Disposal site" means that portion of a land disposal facility that is used for disposal of waste. It consists of disposal units and a buffer zone.

"Disposal unit" means a discrete portion of the disposal site into which waste is placed for disposal. For near-surface disposal, the unit is usually a trench.

"Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

"Diversion" means the unauthorized movement of radioactive material subject to 12VAC5-481-451 to a location different from the material's authorized destination inside or outside of the site at which the material is used or stored.

"Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these regulations, "radiation dose" is an equivalent term.

"Dose commitment" means the total radiation dose to a part of the body that will result from retention in the body of radioactive material. For purposes of estimating the dose commitment, it is assumed that from the time of intake the period of exposure to retained material will not exceed 50 years.

"Dose equivalent" or "H_T" means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

"Dose limits" means the permissible upper bounds of radiation doses established in accordance with these regulations. For purposes of these regulations, "limits" is an equivalent term.

"Dose monitor unit" or "DMU" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

"Dose profile" means the dose as a function of position along a line.

"Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

"Doubly encapsulated sealed source" means a sealed source in which the radioactive material is sealed within an inner capsule and that capsule is sealed within an outer capsule.

"Drive cable" (See "Control cable").

"Effective dose equivalent" or "H_E" means the sum of the products of the dose equivalent (H_T) to each organ or tissue and the weighting factor (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = w_T H_T$).

"Electronic brachytherapy" means a method of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage.

"Electronic brachytherapy device" means the system used to produce and deliver therapeutic radiation including the x-ray tube, the control mechanism, the cooling system, and the power source.

"Electronic brachytherapy source" means the x-ray tube component used in an electronic brachytherapy device.

"Elemental area" means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted. (See also "Picture element").

"Embryo/fetus" means the developing human organism from conception until the time of birth.

"Energy compensation source" or "ECS" means a small sealed source, with an activity not exceeding 3.7 MBq (100 µCi), used within a logging tool, or other tool components, to provide a reference standard to maintain the tool's calibration when in use.

"Engineered barrier" means a manmade structure or device that is intended to improve the land disposal facility's ability to meet the performance objectives in these regulations.

"Enriched uranium" (See "Uranium - natural, depleted, enriched").

"Entrance or access point" means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

"EPA identification number" means the number received by a transporter following application to the Administrator of the U.S. Environmental Protection Agency as required by 40 CFR Part 263.

"Equipment" (See "x-ray equipment").

"Escorted access" means accompaniment while in a security zone by an approved individual who maintains continuous direct visual surveillance at all times over an individual who is not approved for unescorted access.

"Exclusive use" means the sole use by a single consignor of a conveyance for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor.

"Explosive material" means any chemical compound, mixture, or device that produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

"Exposure" means being exposed to ionizing radiation or to radioactive material.

"Exposure head" means a device that locates the gamma radiography sealed source in the selected working position.

"Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

"External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"External dose" means that portion of the dose equivalent received from any source of radiation outside the body.

"Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

"Facility" means the location, building, vehicle, or complex under one administrative control, at which one or more radiation machines are installed, located or used.

"Fail-safe characteristics" means a design feature that causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

"Field emission equipment" means equipment that uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

"Field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

"Field station" means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary jobsites.

"Filter" means material placed in the useful beam to preferentially absorb selected radiations. It also means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to Part XV (12VAC5-481-3380 et seq.) of this chapter.

"Filtering facepiece" or "dusk mask" means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

"Fingerprint orders" means the requirements of 12VAC5-481-451 B or orders issued by the U.S. Nuclear Regulatory Commission or the legally binding requirements issued by agreement states that require fingerprints and criminal history records checks for individuals with unescorted access to Category 1 and Category 2 quantities of radioactive material or safeguards information-modified handling.

"Fissile material" means the radionuclides uranium-233, uranium-235, plutonium-239, and plutonium-241, or any combination of these radionuclides. "Fissile material" means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium and natural uranium or depleted uranium, that has been irradiated in thermal reactors only, are not included in this definition. Certain exclusions from fissile material controls are provided in 10 CFR 71.15.

1. Fissile Class I: A package that may be transported in unlimited numbers and in any arrangement, and that requires no nuclear criticality safety controls during transportation. A transport index is not assigned for purposes of nuclear criticality safety but may be required because of external radiation levels.

2. Fissile Class II: A package that may be transported together with other packages in any arrangement but, for criticality control, in numbers that do not exceed an aggregate transport index of 50. These shipments require no other nuclear criticality safety control during transportation. Individual packages may have a transport index not less than 0.1 and not more than 10.

"Fissile material package" means a fissile material packaging together with its fissile material contents.

"Fit factor" means a quantitative estimate of the fit of a particular respirator to a specific

individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

"Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

"Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the image receptors, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

"Fluoroscopic irradiation time" means the cumulative duration during an examination or procedure of operator-applied continuous pressure to the device, enabling x-ray tube activation in any fluoroscopic mode of operation.

"Fluoroscopy" means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term "radioscopy" in the standards of the International Electrotechnical Commission.

"Focal spot" or "actual" means the area projected on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

"Former Atomic Energy Commission or NRC licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where Atomic Energy Commission or NRC licenses have been terminated.

"Gantry" means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

"Generally applicable environmental radiation standards" means standards issued by the U.S. Environmental Protection Agency under the authority of the Atomic Energy Act of 1954, as amended, (42 USC § 2011 et seq.) that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

"General environment" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, the total terrestrial, atmospheric, and aquatic environments outside the site boundary within which any activity, operation, or process authorized by a general or specific license issued under Part XVI, is performed.

"General purpose radiographic x-ray system" means any radiographic x-ray system that, by design, is not limited to radiographic examination of specific anatomical regions.

"Generator" means a licensee who (i) is a waste generator as defined in this chapter, or (ii) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (42 USC § 2021) (e.g., waste generated as a result of decontamination or recycle activities).

"Gonad shield" means a protective barrier for the testes or ovaries.

"Gray" or "Gy" means the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule per kilogram (100 rad).

"Guide tube (protection sheath)" means a flexible or rigid tube, or "J" tube, for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

"Half-value layer" or "HVL" means the thickness of a specified material that attenuates the beam of radiation to an extent that the AKR is reduced by one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

"Hand-held radiographic unit" means x-ray equipment that is designed to be hand-held during operation.

"Hands-on experience" means experience in all of those areas considered to be directly involved in the radiography process, and includes taking radiographs, calibration of survey instruments, operational and performance testing of survey instruments and devices, film development, posting of radiation areas, transportation of radiography equipment, posting of records and radiation area surveillance, etc., as applicable. Excessive time spent in only one or two of these areas, such as film development or radiation area surveillance, should not be counted toward the 2,000 hours of hands-on experience required for a radiation safety officer in 12VAC5-481-1310 B 2 or the hands-on experience for a radiographer as required by 12VAC5-481-1320 A.

"Hazardous waste" means those wastes designated as hazardous by the U.S. Environmental Protection Agency regulations in 40 CFR Part 261.

"Healing arts" means the art or science or group of arts or sciences dealing with the prevention and cure or alleviation of ailments, diseases or infirmities, and has the same meaning as "medicine" when the latter term is used in its comprehensive sense.

"Healing arts screening" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

"Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, such as (kVp) times (mA) times (seconds).

"Helmet"means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

"High integrity container" or "HIC" means a container commonly designed to meet the structural stability requirements of 12VAC5-481-2572 and to meet U.S. Department of Transportation requirements for a Type A package.

"High radiation area" means an area, accessible to individuals, in which radiation levels from

radiation sources external to the body could result in an individual receiving a dose equivalent in excess of one mSv (0.1 rem) in one hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation penetrates.

"Hood" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

"Human use" means the internal or external administration of radiation or radioactive material to human beings.

"Hydrogeologic unit" means any soil or rock unit or zone which by virtue of its porosity or permeability, or lack thereof, has a distinct influence on the storage or movement of groundwater.

"Image intensifier" means a device, installed in its housing, that instantaneously converts an x-ray pattern into a corresponding light image of higher intensity.

"Image receptor" means any device, such as a fluorescent screen, radiographic film, x-ray image intensifier tube, solid-state detector, or gaseous detector that transforms incident x-ray photons either into a visible image or into another form that can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term "image receptor" shall mean the preselected portion of the device.

"Image receptor support device" means, for mammographic systems, that part of the system designed to support the image receptor during mammographic examination and to provide a primary protective barrier.

"Inadvertent intruder" means a person who might occupy the disposal site after closure and engage in normal activities, such as agriculture, dwelling construction, or other pursuits in which an individual might be unknowingly exposed to radiation from the waste.

"Indian tribe" means an Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the U.S. Secretary of the Interior acknowledges to exist as an Indian tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994 (25 USC § 479a).

"Independent certifying organization" means an independent organization that meets the agency's criteria for documenting applicant's training in topics set forth in 12VAC5-481-1320 or equivalent agreement state or NRC regulations.

"Individual" means any human being.

"Individual monitoring" means the assessment of:

1. Dose equivalent (i) by the use of individual monitoring devices or (ii) by the use of survey data; or

2. Committed effective dose equivalent (i) by bioassay or (ii) by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC hours. (See the definition of DAC).

"Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these regulations, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, optically stimulated luminescence (OSL) dosimeters and personal air sampling devices.

"Industrial radiography" means an examination of the structure of materials by the nondestructive method of utilizing ionizing radiation to make radiographic images.

"Inhalation class" (See "Class").

"Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.

"Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the agency.

"Institutional controls" means: (i) permanent markers placed at a disposal site, (ii) public records and archives, (iii) government ownership and regulations regarding land or resource use, and (iv) other methods of preserving knowledge about the location, design, and contents of a disposal system.

"Instrument traceability" (for ionizing radiation measurements) means the ability to show that an instrument has been calibrated at specified time intervals using a national standard or a transfer standard. If a transfer standard is used, the calibration must be at a laboratory accredited by a program that requires continuing participation in measurement quality assurance with the National Institute of Standards and Technology or other equivalent national or international program.

"Intensity modulated radiation therapy" or "IMRT" means radiation therapy that uses nonuniform radiation beam intensities that have been determined by various computer-based optimization techniques.

"Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

"Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

"Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

"Intruder barrier" means a sufficient depth of cover over the waste that inhibits contact with waste and helps to ensure that radiation exposures to an inadvertent intruder will meet the performance objectives set forth in these regulations, or engineered structures that provide equivalent protection to the inadvertent intruder.

"Irradiation" means the exposure of matter to ionizing radiation.

"Irradiator" means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding five grays (500 rads) per hour exist at one meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

"Irradiator operator" means an individual who has successfully completed the training and testing described in 12VAC5-481-2830 and is authorized by the terms of the license to operate the irradiator without a supervisor present.

"Irradiator operator supervisor" means an individual who meets the requirements for an irradiator operator and who physically oversees operation of the irradiator by an individual who is currently receiving training and testing described in 12VAC5-481-2830 .

"Isocenter" means the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center.

"kBq" means kilobecquerel.

"Kerma" or "K" means the quantity defined by the International Commission on Radiation Units and Measurements. The kerma is the quotient of dEtr by dm, where dEtr is the sum of the initial kinetic energies of all charged particles liberated by uncharged particles in a mass dm of materials; thus K=dEtr/dm, in units of J/kg, where the special name for the units of kerma is gray (Gy). When the materials is air, the quantity is referred to as "air kerma."

"Kilovolt" or "kV" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1,000 volts in a vacuum. Current convention is to use kV for photons and keV for electrons.

"Kilovolts peak" (See "Peak tube potential").

"kV" means kilovolts.

"kVp" (See "Peak tube potential").

"kWs" means kilowatt second.

"Land disposal facility" means the land, buildings, structures and equipment that are intended to be used for the disposal of wastes into the subsurface of the land. For purposes of this chapter, a "geologic repository" as defined in 10 CFR Part 60 or 10 CFR Part 63 is not considered a land disposal facility.

"Last image hold radiograph" or "LIH" means an image obtained either by retaining one or more fluoroscopic images, which may be temporarily integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

"Lay-barge radiography" means industrial radiography performed on any water vessel used for laying pipe.

"Lead equivalent" means the thickness of the material in question affording the same

attenuation, under specified conditions, as lead.

"Leakage radiation" means radiation emanating from the diagnostic source assembly or the radiation therapy system except for:

1. The useful beam; and

2. Radiation produced when the exposure switch or timer is not activated.

"Leakage technique factors" means the technique factors associated with the diagnostic source assembly that are used in measuring leakage radiation. They are defined as follows:

1. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, (10 mAs), or the minimum obtainable from the unit, whichever is larger;

2. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential; or

3. For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

"Lens dose equivalent" or "LDE" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 cm (300 mg/cm^2).

"License" means a license issued by the agency in accordance with the regulations adopted by the board.

"Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the agency.

"Licensee" means any person who is licensed by the agency in accordance with these regulations and the Act.

"Light field" means the area illuminated by light, simulating the radiation field.

"Limits" (See "Dose limits").

"Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential as follows:

Percent line-voltage regulation = $100\ (V_n - V_l)/V_l$

where:

V_n = No-load line potential; and

V_l = Load line potential.

"Lixiscope" means a portable light-intensified imaging device using a sealed source.

"Local components" means part of an analytical x-ray system and include areas that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

"Local law-enforcement agency" or "LLEA" means a public or private organization that has been approved by a federal, state, or local government to carry firearms and make arrests, and is authorized and has the capability to provide an armed response in the jurisdiction where the licensed Category 1 or Category 2 quantity of radioactive material is used, stored, or transported.

"Logging assistant" means any individual who, under the personal supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by Part XIV (12VAC5-481-3140 et seq.) of this chapter.

"Logging supervisor" means the individual who uses licensed material or provides personal supervision in the use of licensed material at a temporary jobsite and who is responsible to the licensee for assuring compliance with the requirements of this chapter and the conditions of the license.

"Logging tool" means a device used subsurface to perform well-logging.

"Loose-fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

"Lost or missing licensed material" means licensed (or registered) source of radiation whose location is unknown. This definition includes, but is not limited to, radioactive material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

"Lot tolerance percent defective" means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

"Low specific activity material" or "LSA material" means radioactive material with limited specific activity that is nonfissile or is excepted under 12VAC5-481-2970 C, and that satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material must be in one of three groups:

1. LSA-I

    a. Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radioactive radionuclide that are not intended to be processed for the use of these radionuclides;

    b. Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures;

    c. Radioactive material, for which the A_2 value is unlimited; or

d. Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with 12VAC5-481-3720 .

2. LSA-II

a. Water with tritium concentration up to 0.8 terabecquerel per liter (20.0 Ci/L); or

b. Other material in which the activity is distributed throughout, and the average specific activity does not exceed 1.0 E-04 A_2/g for solids and gases, and 1.0 E-05 A_2/g for liquids.

3. LSA-III

Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of 10 CFR 71.77) in which:

a. The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (e.g., concrete, bitumen, or ceramic);

b. The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for seven days, would not exceed 0.1 A_2; and

c. The estimated average specific activity of the solid does not exceed 2.0 E-03 A_2/g.

"Low toxicity alpha emitters" means natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than 10 days.

"Lung class" (See "Class").

"mA" means milliampere.

"mAs" means milliampere second.

"Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in this section.

"Management" means the chief executive officer or that individual's designee.

"MBq" means megabecquerels.

"Medical event" means an event that meets the criteria in 12VAC5-481-2080 .

"Medical institution" means an organization in which several medical disciplines are

practiced.

"Medical use" means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

"Megavolt" or "MV" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. (Note: current convention is to use MV for photons and MeV for electrons.)

"Member of the public" means an individual except when that individual is receiving an occupational dose.

"Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas.

"Minor" means an individual less than 18 years of age.

"Misadministration" means either:

1. An x-ray teletherapy radiation dose:

    a. Involving the wrong patient;

    b. Involving the wrong mode of treatment;

    c. Involving the wrong treatment site;

    d. Where the calculated total administered dose differs from the total prescribed dose by more than 10% when the treatment consists of three or fewer fractions;

    e. Where the calculated weekly administered dose differs from the weekly prescribed dose by 30%; or

    f. Where the calculated total administered dose differs from the total prescribed dose by more than 20%; or

2. An x-ray brachytherapy radiation dose:

    a. Involving the wrong patient;

    b. Involving the wrong treatment site; or

    c. Where the calculated administered dose differs from the prescribed dose by more than 20%.

"mm" means millimeters.

"Mobile device" means a piece of equipment containing licensed radioactive materials that is either mounted on wheels or casters, or otherwise equipped for moving without a need for disassembly or dismounting, or designed to be hand carried. Mobile devices do not include stationary equipment installed in a fixed location.

"Mobile electronic brachytherapy service" means transportation of an electronic

brachytherapy device to provide electronic brachytherapy at an address that is not the address of record.

"Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

"Mobile x-ray equipment" (See "x-ray equipment").

"Mode of operation" means, for fluoroscopy systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog and digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

"Monitor unit" or "MU" (See "Dose monitor unit").

"Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these regulations, "radiation monitoring" and "radiation protection monitoring" are equivalent terms. For Part XI (12VAC5-481-2330 et seq.) of this chapter, it means observing and making measurements to provide data to evaluate the performance and characteristics of the disposal site.

"Movement control center" means an operation center that is remote from the transport activity and that maintains the position information on the movement of radioactive material, receives reports of attempted attacks or thefts, provides a means for reporting these and other problems to appropriate agencies and can request and coordinate appropriate aid.

"Moving beam radiation therapy" means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation and rotational therapy.

"Multiple tomogram system" means a computed tomography x-ray system that obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

"NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.

"National Sealed Source and Device Registry" or "SSDR" means the national registry that contains the registration certificates, maintained by the NRC, that summarize the radiation safety information for sealed sources and devices, and describes the licensing and use conditions approved for the product.

"Nationally tracked source" means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in 12VAC5-481-3780 . In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and that is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

"Natural radioactivity" means radioactivity of naturally occurring nuclides.

"Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes, which is essentially 100 weight percent thorium-232.

"Natural uranium" (See "Uranium - natural, depleted, enriched").

"Near-surface disposal facility" means a land disposal facility in which waste is disposed of within approximately the upper 30 meters of the earth's surface.

"Negative pressure respirator" or "tight fitting" means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

"No-later-than arrival time" means the date and time that the shipping licensee and receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than arrival times may not be more than six hours after the estimated arrival time for shipments of Category 2 quantities of radioactive material.

"Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \oplus \overline{CS} \oplus s}{\mu_w}$$

where:

$\overline{CS}$ = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

s = Standard deviation of the CTN of picture elements in a specified area of the CT image.

"Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

"Non-image-intensified fluoroscopy" means fluoroscopy using only a fluorescent screen.

"Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these regulations, "deterministic effect" is an equivalent term.

"NORM" means any naturally occurring radioactive material. It does not include accelerator produced, byproduct, source, or special nuclear material.

"Normal form radioactive material" means radioactive material that has not been demonstrated to qualify as special form radioactive material.

"Normal operating procedures" mean step-by-step instructions necessary to accomplish the analysis. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant (or licensee), and data recording procedures, which are related to radiation safety.

"Nominal treatment distance" means:

1. For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

2. For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.

"NRC Forms 540, 540A, 541, 541A, 542, and 542A" means official NRC forms referenced in this chapter. Licensees need not use originals of these NRC Forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, NRC Forms 541 (and 541A) and NRC Forms 542 (and 542A) may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

"Nuclear Regulatory Commission" or "NRC" means the NRC or its duly authorized representatives.

"Nuclear waste" means a quantity of source, byproduct or special nuclear material (the definition of nuclear waste in this chapter is used in the same way as in 49 CFR 173.403) required to be in NRC-approved specification packaging while transported to, through or across a state boundary to a disposal site, or to a collection point for transport to a disposal site.

"Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties for the licensee or registrant involve exposure to sources of radiation, whether or not the sources of radiation are in the possession of the licensee, registrant, or other person. Occupational dose does not include doses received from

background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 12VAC5-481-1870 , from voluntary participation in medical research programs, or as a member of the public.

"Offshore platform radiography" means industrial radiography conducted from a platform over a body of water.

"Offshore waters" means that area of land and water, beyond the Commonwealth of Virginia's jurisdiction, on or above the U.S. Outer Continental Shelf.

"Open-beam configuration" means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

"Package" means the packaging together with its radioactive contents as presented for transport.

1. Fissile material package or Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package means a fissile material packaging together with its fissile material contents.

2. Type A package means a Type A packaging together with its radioactive contents. A Type A package is defined and must comply with the DOT regulations in 49 CFR Part 173.

3. Type B package means a Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 lbs/in^2) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in 10 CFR 71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in 49 CFR Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in 10 CFR 71.19.

"Packaging" means the assembly of components necessary to ensure compliance with the packaging requirements of these regulations. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

"Panoramic dry-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators

in which only a narrow beam of radiation is produced for performing irradiations.

"Panoramic irradiator" means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

"Panoramic wet-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

"Particle accelerator" (See "Accelerator").

"Patient" means an individual or animal subjected to healing arts examination, diagnosis, or treatment.

"PBL" (See "Positive beam limitation").

"Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

"Periodic quality assurance check" means a procedure that is performed to ensure that a previous calibration continues to be valid.

"Permanent radiographic installation" means an enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed.

"Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, department of the Commonwealth other than the Department of Health, political subdivision of the Commonwealth, any other state or political subdivision or department thereof, and any legal successor, representative, agent, or department of the foregoing, but not including federal government agencies.

"Personal supervision" means guidance and instruction by the supervisor who is physically present at the jobsite and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required. In radiography it means guidance and instruction provided to a radiographer trainee by a radiographer instructor who is present at the site, in visual contact with the trainee while the trainee is using sources of radiation, and in such proximity that immediate assistance can be given if required.

"Personnel monitoring equipment" (See "Individual monitoring devices").

"Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

"Physical description" means the items called for on NRC Form 541 to describe a low-level radioactive waste.

"Pool irradiator" means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

"Pharmacist" means an individual licensed by this state to compound and dispense drugs, prescriptions, and poisons.

"Physician" means an individual licensed by this state to prescribe drugs in the practice of medicine.

"Picture element" means an elemental area of a tomogram.

"PID" (See "Position indicating device").

"Pigtail" (See "Source assembly").

"Pill" (See "Sealed source").

"Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

"Portable x-ray equipment" (See "x-ray equipment").

"Position indicating device" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

"Positive beam limitation" means the automatic or semi-automatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

"Positron emission tomography radionuclide production facility" or "PET" means a facility operating a cyclotron or other particle accelerator for the purpose of producing radionuclides that decay by positron emission.

"Positive pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

"Powered air-purifying respirator" or "PAPR" means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

"Practical examination" means a demonstration through application of the safety rules and principles in industrial radiography including use of all procedures and equipment to be used by radiographic personnel.

"Practical range of electrons" corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung x-rays. A further explanation may be found in "Clinical Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25" (Medical Physics 18(1): 73-109, Jan/Feb. 1991) and ICRU Report 35, "Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV", International Commission on Radiation Units and Measurements, September 15, 1984.

"Preceptor" means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a radiation safety officer.

"Prescribed dosage" means the quantity of radiopharmaceutical activity as documented:

1. In a written directive; or

2. Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

"Prescribed dose" means:

1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

2. For teletherapy, the total dose and dose per fraction as documented in the written directive. The prescribed dose is an estimation from measured data from a specified therapeutic machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique; or

3. For brachytherapy, either the total source strength and exposure time, or the total dose, as documented in the written directive.

"Pressure demand respirator" means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

"Primary beam" means radiation that passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.

"Primary dose monitoring system" means a system that will monitor the useful beam during irradiation and that will terminate irradiation when a preselected number of dose monitor units have been delivered.

"Primary protective barrier" means the material, excluding filters, placed in the useful beam to reduce the radiation exposure (beyond the patient and cassette holder) for protection barriers.

"Principal activities," as used in this chapter, means activities authorized by the license that are essential to achieving the purposes for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

"Private inspector" means an individual who meets the requirements set forth in 12VAC5-481-340 and who has demonstrated to the satisfaction of the agency that such individual possesses the knowledge, training and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs.

"Product" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, something produced, made, manufactured, refined, or benefited.

"Product conveyor system" means a system for moving the product to be irradiated to, from,

and within the area where irradiation takes place.

"Projection sheath" (See "Guide tube").

"Projector" (See "Radiographic exposure device").

"Protective apron" means an apron made of radiation-attenuating or absorbing materials used to reduce exposure to radiation.

"Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

"Public dose" means the dose received by a member of the public from exposure to sources of radiation released by the licensee or registrant, or to any other source of radiation under the control of the licensee or registrant. "Public dose" does not include occupational dose, or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 12VAC5-481-1870 , or from voluntary participation in medical research programs.

"Pulsed mode" means operation of the x-ray system such that the x-ray tube is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.

"Pyrophoric material" means any liquid that ignites spontaneously in dry or moist air at or below 130°F (54.4°C) or any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or that can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

"Qualified inspector" means an individual who is granted professional privileges based on education and experience to provide clinical services in diagnostic and therapeutic medical physics.

"Qualified medical physicist" means an individual qualified in accordance with 12VAC5-481-3390 D.

"Qualitative fit test" or "QLFT" means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

"Quality factor" or "Q" means the modifying factor, that is referenced in 12VAC5-481-240 , that is used to derive dose equivalent from absorbed dose.

"Quantitative fit test" or "QNFT" means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

"Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in

consecutive quarters.

"Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray).

"Radiation" means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these regulations, ionizing radiation is an equivalent term. Radiation, as used in these regulations, does not include nonionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

"Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

"Radiation dose" (See "Dose").

"Radiation field" (See "Useful beam").

"Radiation head" means the structure from which the useful beam emerges.

"Radiation machine" means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.

"Radiation room" means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

"Radiation safety officer" or "RSO" means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations and has been assigned such responsibility by the licensee or registrant.

"Radiation safety officer for industrial radiography" means an individual with the responsibility for the overall radiation safety program on behalf of the licensee or registrant and who meets the requirements of 12VAC5-481-1310 .

"Radiation safety officer for medical" means an individual who meets the requirements of 12VAC5-481-1750 and 12VAC5-481-1790 or is identified as an RSO on: a medical use license issued by the agency, NRC or another agreement state, or a medical use permit issued by an NRC masters material licensee.

"Radiation therapy physicist" means an individual qualified in accordance with 12VAC5-481-340 .

"Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

"Radiation therapy system" means a device that delivers radiation to a specific area of the body where cancer cells or tumors are located.

"Radioactive material" means any solid, liquid, or gas which emits radiation spontaneously.

"Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

"Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

"Radiobioassay" (See "Bioassay").

"Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

"Radiographer" means any individual who performs or who, in attendance at the site where the sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of the agency's regulations and the conditions of the license or registration.

"Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met the radiation safety, testing, and experience criteria in 12VAC5-481-1320 .

"Radiographer instructor" means any radiographer who has been authorized by the agency to provide on-the-job training to radiographer trainees in accordance with Part V (12VAC5-481-1170 et seq.) of this chapter.

"Radiographer trainee" means any individual who, under the personal supervision of a radiographer instructor, uses sources of radiation, related handling tools, or radiation survey instruments during the course of his instruction.

"Radiographer's assistant" means any individual who under the direct supervision of a radiographer, uses radiographic exposure devices, sources of radiation, related handling tools, or radiation survey instruments in industrial radiography.

"Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

"Radiographic operations" means all activities performed with a radiographic exposure device, or with a radiation machine. Activities include using, transporting except by common or contract carriers, or storing at a temporary job site, performing surveys to confirm the adequacy of boundaries, setting up equipment, and any activity inside restricted area boundaries. Transporting a radiation machine is not considered a radiographic operation.

"Radiographic personnel" means any radiographer, radiographer instructor, or radiographer trainee.

"Radiography" means:

1. For radioactive materials: See "Industrial radiography."

2. For x-ray: A technique for generating and recording an x-ray pattern for the purpose of providing the user with an image after termination of the exposure.

"Rating" means the operating limits as specified by the component manufacturer.

"Reasonably maximally exposed individual" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, a representative of a population who is exposed to TENORM at the maximum TENORM concentration measured in environmental media found at a site along with reasonable maximum case exposure assumptions. The exposure is determined by using maximum values for one or more of the most sensitive parameters affecting exposure, based on cautious but reasonable assumptions, while leaving the others at their mean value.

"Recording" means producing a retrievable form of an image resulting from x-ray photons.

"Redundant beam monitoring system" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a preselected number of dose monitor units.

"Reference man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health employees to standardize results of experiments and to relate biological insult to a common base. A description of the reference man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."

"Reference plane" means a plane that is displaced from and parallel to the tomographic plane.

"Registrant" means any person who is registered with the agency and is legally obligated to register with the agency pursuant to these regulations and the Act.

"Registration" means registration with the agency in accordance with the regulations adopted by the agency.

"Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100 - 189.

"Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).

"Reportable event" means the administration of either:

1. A diagnostic x-ray exposure where an actual or suspected acute or long-term functional damage to an organ or a physiological system has occurred. Exempt from this reporting requirement is any event when any functional damage to a patient organ or a physiological system that was an expected outcome when the causative procedures were prescribed;

2. A procedure where the patient or operator is injured as a result of a mechanical injury;

3. A teletherapy x-ray or electron dose where the calculated weekly administered dose differs from the weekly prescribed dose by 15% or more; or

4. A brachytherapy x-ray dose where the calculated administered dose differs from the prescribed dose by 10% or more.

"Research and development" means (i) theoretical analysis, exploration, or experimentation; or (ii) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstrative purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

"Residential location" means any area where structures in which people lodge or live are located, and the grounds on which such structures are located including, but not limited to, houses, apartments, condominiums, and garages.

"Residual radioactive material" means (i) waste (that the U.S. Secretary of Energy determines to be radioactive) in the form of tailings resulting from the processing of ores for the extraction of uranium and other valuable constituents of the ores and (ii) other waste (that the U.S. Secretary of Energy determines to be radioactive) at a processing site that relates to such processing, including any residual stock of unprocessed ores or low-grade materials. This term is used only with respect to materials at sites subject to remediation under Title I of the Uranium Mill Tailings Radiation Control Act of 1978, as amended.

"Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive materials at the site and previous burials at the site, even if those burials were made in accordance with the provisions of Part IV (12VAC5-481-600 et seq.) of this chapter.

"Residual waste" means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

"Respiratory protective device" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

"Restricted area" means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

"Reviewing official" means the individual who shall make the trustworthiness and reliability determination of an individual to determine whether the individual may have, or continue to have, unescorted access to the Category 1 or Category 2 quantities of radioactive materials that are possessed by the licensee.

"Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58E-4 coulombs per kilogram of air (see "Exposure" and 12VAC5-481-240).

"S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.

"Sabotage" means deliberate damage, with malevolent intent, to a Category 1 or Category 2 quantity of radioactive material, a device that contains a Category 1 or Category 2 quantity of radioactive material, or the components of the security system.

"Safe haven" means a readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the local law-enforcement authorities.

"Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

"Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

"Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

"Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

"Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

"Scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

"Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of any radioactive material.

"Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

"Security zone" means any temporary or permanent area determined and established by the licensee for the physical protection of Category 1 or Category 2 quantities of radioactive material.

"Seismic area" means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10%, as designated by the United States Geological Survey.

"Self-contained breathing apparatus" or "SCBA" means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

"Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

"Shallow dose equivalent" or "H_s," which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm2).

"Shielded position" means the location within the radiographic exposure device or storage container which, by manufacturer's design, is the proper location for storage of the sealed source.

"Shielded-room radiography" means industrial radiography conducted in a room shielded so that radiation levels at every location on the exterior meet the limitations specified in 12VAC5-481-640 .

"Shipper" means the licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

"Shipping paper" means NRC Form 540 and, if required, NRC Form 540A, which includes the information required by the U.S. Department of Transportation in 49 CFR Part 172.

"Shutter" means a device attached to the tube housing assembly which can intercept the entire cross sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

"SI" means the abbreviation for the International System of Units.

"SID" (See "Source-image receptor distance").

"Sievert" or "Sv" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

"Simulator" or "radiation therapy simulation system" means any x-ray system intended for localizing the volume to be exposed during radiation therapy and reproducing the position and size of the therapeutic irradiation field.

"Single tomogram system" means a CT x-ray system that obtains x-ray transmission data during a scan to produce a single tomogram.

"Site area emergency" means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

"Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

"Site closure and stabilization" means those actions that are taken upon completion of

operations that prepare the disposal site for custodial care and that assure that the disposal site will remain stable and will not need ongoing active maintenance.

"Source" means the focal spot of the x-ray tube.

"Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may include a ballstop to secure the source in the shielded position.

"Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources.

"Source holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.

"Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

"Source material" means:

1. Uranium or thorium, or any combination thereof, in any physical or chemical form; or

2. Ores that contain by weight one-twentieth of 1.0% (0.05%) or more of uranium, thorium or any combination of uranium and thorium. Source material does not include special nuclear material.

"Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

"Source-skin distance" or "SSD" means the distance from the source to the center of the entrant x-ray field in the plane tangent to the patient's skin surface.

"Source traceability" means the ability to show that a radioactive source has been calibrated either by the national standards laboratory of the National Institute of Standards and Technology, or by a laboratory that participates in a continuing measurement quality assurance program with National Institute of Standards and Technology or other equivalent national or international program.

"Special form radioactive material" means radioactive material that satisfies the following conditions:

1. It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

2. The piece or capsule has at least one dimension not less than five millimeters (0.2 in.); and

3. It satisfies the test requirements specified by the NRC. A special form encapsulation designed in accordance with the NRC requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation

either designed or constructed after April 1, 1998, must meet requirements of this definition applicable at the time of its design or construction.

"Special nuclear material" means:

1. Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material the NRC, pursuant to the provisions of § 51 of the Atomic Energy Act of 1954, as amended, (42 USC § 2071) determines to be special nuclear material, but does not include source material; or

2. Any material artificially enriched by any of the foregoing but does not include source material.

"Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

(175 grams contained U235/350) + (50 grams U – 233/200) + (50 grams Pu/200) = 1

"Specific activity of a radionuclide" means the radioactivity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

"Spot film" means a radiograph that is made during a fluoroscopic examination to permanently record conditions that exist during that fluoroscopic procedure.

"Spot-film device" means a device intended to transport or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

"Stability" means structural stability.

"State inspector" means an employee of the Virginia Department of Health designated to perform those duties or functions assigned the Radiological Health Program.

"Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

"Stationary x-ray equipment" (See "x-ray equipment").

"Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

For purposes of this chapter, "probabilistic effect" is an equivalent term.

"Storage" means a condition in which a device or source is not being used for an extended period of time, and has been made inoperable.

"Storage area" means any location, facility, or vehicle that is used to store and secure a radiographic exposure device, a radiation machine, or a storage container when it is not used for radiographic operations. Storage areas are locked or have a physical barrier to prevent accidental exposure, tampering, or unauthorized removal of the device, machine, or container.

"Storage container" means a device in which sealed sources or radiation machines are secured and stored.

"Stray radiation" means the sum of leakage and scattered radiation.

"Subsurface tracer study" means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation.

"Supplied-air respirator," "airline respirator," or "SAR" means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

"Surface contaminated object" or "SCO" means a solid object that is not itself classed as radioactive material, but that has radioactive material distributed on any of its surfaces. An SCO must be in one of two groups with surface activity not exceeding the following limits:

1. SCO-I: A solid object on which:

   a. The nonfixed contamination on the accessible surface averaged over 300 cm^2, or the area of the surface if less than 300 cm^2, does not exceed four becquerel per cm^2 (1 E-04 $\mu Ci/cm^2$) for beta and gamma and low toxicity alpha emitters, or 0.4 becquerel per cm^2 (1 E-05 $\mu Ci/cm^2$) for all other alpha emitters;

   b. The fixed contamination on the accessible surface averaged over 300 cm^2, or the area of the surface if less than 300 cm^2, does not exceed 4 E+04 becquerel per cm^2 (1.0 $\mu Ci/cm^2$) for beta and gamma and low toxicity alpha emitters, or 4 E+03 becquerel per cm^2 (0.1 $\mu Ci/cm^2$) for all other alpha emitters; and

   c. The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2, or the area of the surface if less than 300 cm^2, does not exceed 4 E+04 becquerel per cm^2 (1 $\mu Ci/cm^2$) for beta and gamma and low toxicity alpha emitters, or 4 E+03 Becquerel per cm^2 (0.1 $\mu Ci/cm^2$) for all other alpha emitters.

2. SCO-II: A solid object on which the limits for SCO-I are exceeded and on which:

   a. The nonfixed contamination on the accessible surface averaged over 300 cm^2, or the area of the surface if less than 300 cm^2, does not exceed 400 becquerel per cm^2 (1 E-02 $\mu Ci/cm^2$) for beta and gamma and low toxicity alpha emitters or 40 becquerel per cm^2 (1 E-03 $\mu Ci/cm^2$) for all other alpha emitters;

b. The fixed contamination on the accessible surface averaged over 300 cm^2, or the area of the surface if less than 300 cm^2, does not exceed 8 E+05 becquerel per cm^2 (20 $\mu Ci/cm^2$) for beta and gamma and low toxicity alpha emitters, or 8 E+04 becquerel per cm^2 (2 $\mu Ci/cm^2$) for all other alpha emitters; and

c. The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2, or the area of the surface if less than 300 cm^2, does not exceed 8 E+05 becquerel per cm^2 (20 $\mu Ci/cm^2$) for beta and gamma and low toxicity alpha emitters, or 8 E+04 becquerel per cm^2 (2 $\mu Ci/cm^2$) for all other alpha emitters.

"Surveillance" means monitoring and observation of the disposal site for purposes of visual detection of need for maintenance, custodial care, evidence of intrusion, and compliance with other license and regulatory requirements.

"Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

"Tabletop, stationary" means a tabletop that, when assembled for use, is incapable of movement with respect to its supporting structure within the plane of the tabletop.

"Target" means that part of an x-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

"Target-skin distance" or "TSD" means the distance measured along the beam axis from the center of the front surface of the x-ray target or electron virtual source, or both, to the surface of the irradiated object or patient.

"Technologically enhanced naturally occurring radioactive material" or "TENORM" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, naturally occurring radionuclides whose concentrations are increased by or as a result of past or present human practices. TENORM does not include background radiation or the natural radioactivity of rocks or soils. TENORM does not include uranium or thorium in "source material" as defined in the AEA and NRC regulations.

"Technique factors" means the following conditions of operation:

1. For capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliampere-seconds (mAs);

2. For field emission equipment rated for pulsed operation, peak tube potential in kilovolts (kV), and number of x-ray pulses;

3. For CT equipment designed for pulsed operation, peak tube potential in kilovolts (kV), scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in milliampere-seconds (mAs);

4. For CT equipment not designed for pulsed operation, peak tube potential in kilovolts (kV), and either tube current in milliamperes (mA) and scan time in seconds, or the product of tube current and exposure time in milliampere-seconds (mAs) and the scan time when the scan time and exposure time are equivalent; and

5. For all other equipment, peak tube potential in kilovolts (kV), and either tube current in milliamperes (mA) and exposure time in seconds, or the product of tube current and exposure time in milliampere-seconds (mAs).

"Telemetric position monitoring system" means a data transfer system that captures information by either instrumentation or measuring devices, or both, about the location and status of a transport vehicle or package between the departure and destination locations.

"Teletherapy physicist" means an individual identified as a qualified teletherapy physicist on an agency license.

"Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"Temporary job site" means any location where industrial radiography, wireline service, well-logging, portable gauge or x-ray fluorescence use is performed and where licensed material may be stored other than those locations of use authorized on the license.

"Tenth-value layer" or "TVL" means the thickness of a specified material that attenuates x-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

"Test" means the process of verifying compliance with an applicable regulation.

"Therapeutic radiation machine" means x-ray or electron-producing equipment designed and used for external beam radiation therapy. For the purpose of this chapter, devices used to administer electronic brachytherapy shall also be considered therapeutic radiation machines.

"These regulations" mean all parts of this chapter.

"Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

"Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

"Tomographic plane" means that geometric plane that is identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

"Total effective dose equivalent" or "TEDE" means the sum of the effective dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

"Total organ dose equivalent" or "TODE" means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in 12VAC5-481-1040 .

"Traceable to a National Standard" (See "Instrument traceability" or "Source traceability").

"Transfer" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, the physical relocation of NORM containing materials not directly associated with commercial distribution within a business's operation or between general or specific licensees. This term does not include a change in legal title to NORM containing materials that does not involve physical movement of those materials.

"Transport container" means a package that is designed to provide radiation safety and security when sealed sources are transported and that meets all applicable requirements of the U.S. Department of Transportation.

"Transport index" or "TI" means the dimensionless number, rounded up to the next tenth, placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at one meter (3.3 feet) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at one meter (3.3 feet)).

"Treatment site" means the correct anatomical description of the area intended to receive a radiation dose, as described in a written directive.

"Tribal official" means the highest ranking individual that represents tribal leadership, such as the chief, president, or tribal council leadership.

"Tritium neutron generator target source" means a tritium source used within a neutron generator tube to produce neutrons for use in well-logging applications.

"Trustworthiness and reliability" means characteristics of an individual considered dependable in judgment, character, and performance, such that unescorted access to Category 1 or Category 2 quantities of radioactive material by that individual does not constitute an unreasonable risk to the public health and safety or security. A determination of trustworthiness and reliability for this purpose is based upon the results from a background investigation.

"Tube" means an x-ray tube, unless otherwise specified.

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage or filament transformers and other appropriate elements when such are contained within the tube housing.

"Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

"Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form

radioactive material, where A_1 and A_2 are given in Table 1 of 12VAC5-481-3770 F or may be determined by procedures described in 12VAC5-481-3770 A through E.

"Type B quantity" means a quantity of radioactive material greater than a Type A quantity.

"Underwater irradiator" means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

"Underwater radiography" means radiographic operations performed when the radiographic exposure device or radiation machine or related equipment are beneath the surface of the water.

"Unescorted access" means solitary access to an aggregated Category 1 or Category 2 quantity of radioactive material or the devices that contain the material.

"Uniform Low-Level Radioactive Waste Manifest" or "uniform manifest" means the combination of NRC Forms 540 and 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

"Unirradiated uranium" means uranium containing not more than 2×10^3 Bq of plutonium per gram of uranium-235, not more than 9×10^6 Bq of fission products per gram of uranium-235, and not more than 5×10^{-3} g of uranium-236 per gram of uranium-235.

"Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining. Processing does not include sieving or encapsulating of ore or preparation of samples for laboratory analysis.

"Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant. For purposes of these regulations, "uncontrolled area" is an equivalent term.

"Uranium - natural, depleted, enriched"

1. "Natural uranium" means uranium with the naturally occurring distribution of uranium isotopes, which is approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238.

2. "Depleted uranium" means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

3. "Enriched uranium" means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

"Uranium sinker bar" means a weight containing depleted uranium used to pull a logging tool down toward the bottom of a well.

"Useful beam" means the radiation that passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

"User seal check" or "fit check" means an action conducted by the respirator user to determine

if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

"Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

"Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of five Gy (500 rad) in one hour at one meter from a source of radiation or one meter from any surface that the radiation penetrates.

"Virtual simulator" means a computed tomography (CT) unit used in conjunction with relevant software that recreates the treatment machine and that allows import, manipulation, display, and storage of images from CT or other imaging modalities, or both.

"Virtual source" means a point from which radiation appears to originate.

"Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

"Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.

"Waste" means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in subdivisions 2, 3, and 4 of the definition of byproduct material.

"Waste collector" means an entity, operating under a specific license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

"Waste description" means the physical, chemical and radiological description of a low-level radioactive waste as called for on NRC Form 541.

"Waste generator" means an entity, operating under a license, that (i) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (ii) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a "waste generator" if the transfer of low-level radioactive waste from its facility is defined as "residual waste."

"Waste handling licensees" mean persons licensed to receive and store radioactive wastes prior to disposal or persons licensed to dispose of radioactive waste.

"Waste processor" means an entity, operating under a specific license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste

generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

"Waste type" means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically defined media).

"Wedge filter" means a filter that effects continuous change in transmission over all or a part of the useful beam.

"Week" means seven consecutive days starting on Sunday.

"Weighting factor" or "w_T" for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

Organ Dose Weighting Factors	
Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30[a/]
Whole Body	1.00[b/]
[a/]0.30 results from 0.06 for each of five"remainder" organs, excluding the skin and the lens of the eye,that receive the highest doses.	
[b/]For the purpose of weighting the external wholebody dose for adding it to the internal dose, a single weighting factor, w_T= 1.0, has been specified. The use of other weighting factors for externalexposure will be approved on a case-by-case basis until such time as specificguidance is issued.	

"Well-bore" means a drilled hole in which wireline service operations or subsurface tracer studies are performed.

"Well-logging" means all operations involving the lowering and raising of measuring devices

or tools that may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well or adjacent formations.

"Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

"Wireline" means a cable containing one or more electrical conductors that is used to lower and raise logging tools in the well-bore.

"Wireline service operation" means any evaluation or mechanical service that is performed in the well-bore using devices on a wireline.

"Worker" means an individual engaged in work under a license or registration issued by the agency and controlled by a licensee or registrant but does not include the licensee or registrant.

"Working level" or "WL" means any combination of short-lived radon daughters in one liter of air that will result in the ultimate emission of 1.3E+5 MeV of potential alpha particle energy. The short-lived radon daughters of radon-222 are polonium-218, lead-214, bismuth-214, and polonium-214; and those of radon-220 are polonium-216, lead-212, bismuth-212, and polonium-212.

"Working level month" or "WLM" means an exposure to one working level for 170 hours. Two thousand working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

"Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in subdivision 6 of this definition, containing the following information:

1. For any administration of quantities greater than 1.11 megabecquerels (30 mCi) of sodium iodide I-125 or I-131: the radionuclide, and dosage;

2. For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

3. For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

4. For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;

5. For high-dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, and total dose; or

6. For all other brachytherapy,

a. Prior to implantation: the radionuclide, number of sources, and source strengths; and

b. After implantation but prior to completion of the procedure: the radionuclide, treatment site, and total source strength and exposure time (or, equivalently, the total

dose).

"X-ray control" means a device that controls input power to the x-ray high-voltage generator or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

"X-ray exposure control" means a device, switch, button or other similar means by which an operator initiates or terminates the radiation exposure. The x-ray exposure control may include such associated equipment as timers and back-up timers.

"X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

1. "Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

2. "Portable x-ray equipment" means x-ray equipment designed to be hand-carried.

3. "Stationary x-ray equipment" means x-ray equipment that is installed in a fixed location.

"X-ray field" means that area of the intersection of the useful beam and any one of the sets of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the AKR is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device that transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tubes, high-voltage switches, electrical protective devices, and other appropriate elements.

"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components that function with the system are considered integral parts of the system.

"X-ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, fluoroscopic image receptor, or spot-film device beneath the tabletop.

"X-ray tube" means any electron tube that is designed for the conversion of electrical energy into x-ray energy.

"Year" means the period of time beginning in January used to determine compliance with the provisions of this chapter. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year. If a licensee or registrant changes in a year, the licensee or registrant shall assure that no day is omitted or duplicated in consecutive years.

12VAC5-481-20. Scope.

Except as otherwise specifically provided, these regulations apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation; provided, however, that nothing in these regulations shall apply to any person to the extent such person is subject to regulation by the NRC. Attention is directed to the fact that regulation by the state of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the state and the NRC and to 10 CFR Part 150 of the commission's regulations.

To reconcile differences between this chapter and the incorporated sections of federal regulations and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of the federal regulations:

1. A reference to "NRC" or "Commission" means agency.

2. A reference to "NRC or agreement state" means agency, NRC or another agreement state.

3. The definition of "sealed source" includes NARM.

4. A reference to "byproduct material" includes NARM.

5. Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the agency and, for NRC licenses, to the NRC until agreement state status is in effect.

12VAC5-481-30. Deliberate Misconduct.

A. No person may do any of the following:

1. Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, registrant or applicant under this chapter to be in violation of any rule or order of the agency; or any term, condition or limitation of any license or registration issued by the agency under this chapter.

2. Deliberately submit to the agency, a licensee, registrant or applicant under this chapter; or a contractor or subcontractor of a licensee, registrant or applicant under this chapter; any information that the person knows to be incomplete or inaccurate.

B. Deliberate misconduct by a person means an intentional act or omission that the person knows:

1. Would cause a licensee, certificate of registration holder or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the agency; or

2. Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate of registration holder, applicant, contractor, or subcontractor.

12VAC5-481-40. (Reserved.)

12VAC5-481-50. (Reserved.)

12VAC5-481-60. (Reserved.)

12VAC5-481-70. (Reserved.)

12VAC5-481-80. (Reserved.)

12VAC5-481-90. Exemptions from Regulatory Requirements.

A. The agency may, upon application or upon its own initiative, grant such exemptions or exceptions from the requirements of these regulations as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

B. Any Department of Energy contractor or subcontractor and any NRC contractor or subcontractor of the following categories operating within this state is exempt from these regulations to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers, or acquires sources of radiation:

1. Prime contractors performing work for the Department of Energy at United States government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

2. Prime contractors of the Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

3. Prime contractors of the Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and

4. Any other prime contractor or subcontractor of the Department of Energy or of the NRC when the state and the NRC jointly determine:

a. That the exemption of the prime contractor or subcontractor is authorized by law; and

b. That, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

12VAC5-481-100. Records.

A. Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation as follows:

1. As long as the material is possessed and for three years following transfer or disposition of the radioactive material.

2. Until the agency terminates the license for the licensee who transferred the material.

3. Until the agency terminates the license for the licensee who disposes the material.

B. If radioactive material is combined or mixed with other licensed material and subsequently treated in a manner that makes direct correlation of a receipt record with a transfer, export, or disposition record impossible, the licensee may use evaluative techniques (such as first-in-first-out) to make the records that are required by this section account for 100% of the material received.

C. Additional record requirements are specified elsewhere in these regulations. If the record retention period is not specified, the record shall be maintained for a period of three years.

12VAC5-481-110. Inspections and Enforcement.

A. Each licensee and registrant shall afford the agency at all reasonable times opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

B. Each licensee and registrant shall make available to the agency for inspection, upon reasonable notice, records maintained pursuant to these regulations.

C. Enforcement.

1. Whenever the department finds, following inspection and examination, that a source of radiation as constructed, operated or maintained results in a violation of this article or of any rules promulgated under this article, the department shall:

a. Notify the person in control of the source of radiation as to the nature of the violation; and

b. Specify a time frame for termination or abatement of the violation, including a deadline by which the source of the violation shall be reconstructed, operated, or maintained in compliance with this article and any regulations promulgated pursuant to this article.

2. Upon failure to comply within the time frame specified by the department for termination or abatement of the violation, the department may revoke the license, and pursue penalties or enforcement in accordance with § 32.1-27 of the Code of Virginia.

3. Whenever, in the judgment of the department, any person has engaged in or is about to engage in any acts or practices that constitute or will constitute an emergency, hazard to health and safety, or a violation of any provision of this article, or any rule, regulation or order issued thereunder, and at the request of the commissioner, the Attorney General may make application to the appropriate court for an order enjoining such acts or practices, or for an order directing compliance, and upon a showing by the department that such person has engaged or is about to engage in any such acts or practices, a permanent or temporary injunction, restraining order, or other order may be granted.

4. In addition to the provisions of § 32.1-27 of the Code of Virginia, any person who violates any provisions of this article or any order or regulation adopted pursuant thereto shall, upon such finding by a court of competent jurisdiction, be assessed a civil penalty of

not more than $10,000 for each day of such violation. All penalties under this section shall be recovered in a civil action brought by the Attorney General in the name of the Commonwealth. Civil penalties collected pursuant to this section shall be paid into the state treasury and credited to the Radioactive Material Perpetual Care Trust Fund created pursuant to § 32.1-232 of the Code of Virginia.

5. In addition to the provisions of § 32.1-25 of the Code of Virginia, the department shall have the power to enter at all reasonable times, or in cases of an emergency, upon any private or public property for the purpose of determining whether or not there is compliance with or violation of the provisions of this article and rules and regulations issued thereunder, except that entry into areas under the jurisdiction of the federal government shall be effected only with the concurrence of the federal government or its duly designated representative.

12VAC5-481-120. (Reserved)

12VAC5-481-130. Impounding.

Sources of radiation shall be subject to impounding pursuant to § 32.1-238 of the Code of Virginia.

12VAC5-481-140. Prohibited Uses.

A. A hand-held fluoroscopic screen shall not be used with X-ray equipment unless it has been listed in the Registry of Sealed Source and Devices or accepted for certification by the Food and Drug Administration, Center for Devices and Radiological Health.

B. Shoe-fitting fluoroscopic devices shall not be used.

C. No person shall intentionally apply or allow to be applied, either directly or indirectly, radiation to human beings except by, or under the supervision of, a practitioner of the healing arts licensed by this state, except in the case of healing arts screening programs approved in advance by the commissioner. Supervision, as used in this subsection, means the responsibility for and control of quality, radiation safety and technical aspects of the application of radiation to human beings for diagnostic or therapeutic purposes. This prohibition does not apply to persons who are occupationally exposed to radiation or as otherwise provided in these regulations.

12VAC5-481-150. Communications.

All communications and reports concerning this chapter, and applications filed thereunder, should be addressed to the agency at the following address: Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219.

12VAC5-481-160. Effective Date.

The application of these regulations to possess by-product materials, source and special nuclear materials shall not become operative until 30 days after publication in the Virginia Register of a notice of an agreement executed by the Commonwealth of Virginia and the

Federal Government under the provisions of Section 274b of the Atomic Energy Act of 1954, as amended (73 Statute 689). All other applications of the provisions of this chapter shall become effective September 20, 2006.

12VAC5-481-170. Removal of Notices Posted by Agency Prohibited.

Any sign, notice, warning or label affixed by the agency to equipment or facilities of any registrant or licensee shall not be removed, defaced or concealed by any person other than the agency without written permission.

12VAC5-481-180. Tests.

Each licensee and registrant shall perform upon instructions from the agency, or shall permit the agency to perform, such reason%CAable tests as the agency deems appropriate or necessary including, but not limited to, tests of:

1. Sources of radiation;

2. Facilities wherein sources of radiation are used or stored;

3. Radiation detection and monitoring instruments; and

4. Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

12VAC5-481-190. Additional Regulatory Requirements.

The agency may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in these regulations as it deems appropriate or necessary to minimize danger to public health and safety or property.

12VAC5-481-200. (Repealed.)

12VAC5-481-210. Types of Hearings.

Hearings before the board, the commissioner, or their designees shall include any of the following forms depending upon the nature of the controversy and the interests of the parties involved. All concerned parties will be provided with a reasonable notice of any intent to consider any public data, documents or information in making case decisions.

1. Informal conference. An informal conference is a conference with the commissioner or his designee with concerned parties, in person, with counsel or other representatives held in accordance with § 2.2-4019 of the Code of Virginia.

2. Hearing. A hearing is a formal, public proceeding before the commissioner or a designated hearing officer and held in conformance with § 2.2-4020 of the Code of Virginia.

12VAC5-481-220. Hearing As a Matter of Right.

Any licensee or registrant whose licensure, certification or registration has been, or may be affected by any decision of the board or its subordinates in the administration of this chapter

shall have a right to both informal and adjudicatory hearings. The commissioner may require participation in an informal hearing before granting the request for a full adjudicatory hearing.

12VAC5-481-230. Appeal.

A. Any appeal from a denial of a license or certification must be made in writing and received by the agency within 30 days of the date of receipt of notice of the denial.

B. Any request for hearing on the findings on a Notice of Violation pursuant to this regulation must be made in writing and received within 30 days of receipt of the final Notice of Violation.

C. Pursuant to the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), an aggrieved licensee or registrant may appeal a final decision of the commissioner to an appropriate circuit court.

12VAC5-481-240. Units of Exposure and Dose.

A. As used in this chapter, the unit of exposure is the coulomb per kilogram (C/kg) of air and the units of radiation dose are gray (Gy), rad, rem, and sievert. (See 12VAC5-481-10 for definitions.) One roentgen is equal to 2.58E-4 coulomb per kilogram of air.

1. Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

2. Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram or 0.01 joule per kilogram (0.01 Gy).

3. Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).

4. Sievert is the SI unit of any of the quantities as dose equivalent. The dose equivalent is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

B. As used in this chapter, the quality factors for converting absorbed dose to dose equivalent are shown in Quality Factors and Absorbed Dose Equivalencies table in this subsection.

Quality Factors and Absorbed Dose Equivalencies		
Type of Radiation	Quality factor (Q)	Absorbed dose equal to a unit dose equivalent[a]
X, gamma, or beta	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1

High energy protons	10	0.1
[a]Absorbed dose in rad equal to 1 rem or the absorbed dose in gray equal to 1 sievert.		

C. If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rems per hour or sieverts per hour, as provided in subsection B of this section, 1 rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of this chapter, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy of the neutrons, the licensee may use the fluence rate per unit dose equivalent of the approximate Q value from the Mean Quality Factors, Q, and Fluence per Unit Dose Equivalent for Monoenergetic Neutrons table in this subsection to convert a measured tissue dose in rads to dose equivalent in rems.

Mean Quality Factors, Q, and Fluence per Unit Dose Equivalent for Monoenergetic Neutrons			
	Neutron energy (MeV)	Quality factor (Q)[a]	Fluence per unit dose equivalent (neutrons cm^{-2} rem^{-1})[b]
(thermal)	2.5×10^{-8}	2	980×10^{6}
	1×10^{-7}	2	980×10^{6}
	1×10^{-6}	2	810×10^{6}
	1×10^{-5}	2	810×10^{6}
	1×10^{-4}	2	840×10^{6}
	1×10^{-3}	2	980×10^{6}
	1×10^{-2}	2.5	1010×10^{6}
	1×10^{-1}	7.5	170×10^{6}
	5×10^{-1}	11	39×10^{6}
	1	11	27×10^{6}
	2.5	9	29×10^{6}
	5	8	23×10^{6}
	7	7	24×10^{6}
	10	6.5	24×10^{6}
	14	7.5	17×10^{6}

	20	8	16×10^6
	40	7	14×10^6
	60	5.5	16×10^6
	1×10^2	4	20×10^6
	2×10^2	3.5	19×10^6
	3×10^2	3.5	16×10^6
	4×10^2	3.5	14×10^6
[a]Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-cm diameter cylinder tissue-equivalent phantom. [b]Monoenergetic neutrons incident normally on a 30-cm diameter cylinder tissue-equivalent phantom.			

12VAC5-481-250. Units of Radioactivity.

For the purposes of this chapter, activity is expressed in the special unit of curies (Ci) or in the SI unit of becquerels (Bq), their multiples, or their disintegrations (transformations) per unit of time.

1. One becquerel equals 1 disintegration per second (s^{-1}).

2. One curie equals 3.7×10^{10} disintegrations per second equals 3.7×10^{10} becquerels equals 2.22×10^{12} disintegrations per minute.

12VAC5-481-260. Purpose and Scope.

Part II. Registration of Radiation Machine Facilities and Services

A. This part provides for the registration of ionizing radiation machine facilities.

B. In addition to the requirements of this part, all registrants are subject to the applicable provisions of Part 1 (12VAC5-481-10 et seq.), Part IV (12VAC5-481-600 et seq.) and Part X (12VAC5-481-2250 et seq.) of this chapter. In addition, some registrants are subject to provisions of the regulations for Part V (12VAC5-481-1170 et seq.), Part VI (12VAC5-481-1580 et seq.), Part VIII (12VAC5-481-2090 et seq.) and Part IX (12VAC5-481-2140 et seq.) of this chapter.

12VAC5-481-270. Exemptions.

A. Electronic equipment that produces radiation incidental to its operation is exempt from the registration and notification requirements of this part, provided that the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 5 µSv (0.5 mrem) per hour at five centimeters from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

B. Radiation machines while in transit or storage incident thereto are exempt from the requirements of this part.

C. Domestic television receivers are exempt from the requirements of this part.

12VAC5-481-280. Shielding Plan Review.

A. Prior to construction, the floor plans, shielding specifications and equipment arrangement of all new installations, or modifications of existing installations, utilizing ionizing radiation machines shall be available to the agency for review. The required information is found in 12VAC5-481-280 E.

B. The agency may require the applicant to utilize the services of a private inspector to determine the shielding requirements prior to the plan review.

C. The review of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 12VAC5-481-640 and 12VAC5-481-680 through 12VAC5-481-730 .

D. After installation of a radiation machine, the registrant shall maintain for inspection by the agency:

1. The maximum rated technique factors of each machine;

2. A scale drawing of the room in which a stationary radiation machine system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:

a. The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or

b. The type and thickness of materials, or lead equivalency, of each protective barrier.

E. In order for the private inspector to provide an evaluation, technical advice, and approval on shielding requirements for a radiation installation, the following information shall be required.

1. The plans showing, as a minimum, the following:

a. The normal location of the system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors or other openings; the location of the operator's booth; and the location of the control panel;

b. The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;

c. The dimensions of the room(s) concerned;

d. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present;

e. The make and model of the equipment, the maximum technique factors, and the energy waveform (single phase, three phase, etc.);

f. The type of examination(s) or treatment(s) that will be performed with the equipment.

2. Information on the anticipated workload of the system(s) in Ma-minutes per week.

3. A report showing all basic assumptions used in the development of the shielding specifications.

F. The following requirements shall be used in the design for an operator's booth:

1. Space requirements:

a. The operator shall be allotted not less than 0.70 square meter (7.5 square feet) of unobstructed floor space in the booth;

b. The operator's booth may be any geometric configuration with no dimension of less than 0.6 m (2 feet);

c. The space shall be allotted excluding any encumbrance by the X-ray control panel, such as overhang, cables, or other similar encroachments;

d. The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall-mounted image receptor will not reach the operator's position in the booth.

2. Structural requirements:

a. The booth walls shall be permanently fixed barriers of at least 2 m (7 feet) high;

b. When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed;

c. Shielding shall be provided to meet the requirements of Part IV (12VAC5-481-600 et seq.) of this chapter.

3. Radiation exposure control placement: The radiation exposure control for the system shall be fixed within the booth and:

a. Shall allow the operator to remain in the protected area and not be exposed to direct scatter, leakage or primary beam radiation;

b. Shall allow the operator to use the majority of the available viewing windows.

4. Viewing system requirements:

a. Each booth shall have at least one viewing device that will:

(1) Be so placed that the operator can view the patient during any exposure; and

(2) Be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door that allows access to the room cannot be seen from the booth, then outside that door there shall be an "X-ray on" warning sign that will be lighted anytime the rotor of the X-ray tube is activated. Alternatively, an interlock shall be present such that exposures are prevented unless the door is closed.

b. When the viewing system is a window, the following requirements also apply:

(1) The window shall have a viewing area of at least 0.09 square meter (1 square foot); Regardless of size or shape, at least 0.09 square meter (1 square foot) of the window area must be centered no less than 0.6 meter (2 feet) from the open edge of the booth and no less than 1.5 meter (5.0 feet) from the floor;

(2) The window shall have at least the same lead equivalence as that required in the booth's wall in which it is mounted.

c. When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of subdivision 1 of this subsection.

d. When the viewing system is by electronic means:

(1) The camera shall be so located as to accomplish the general requirements of subdivision 1 of this subsection; and

(2) There shall be an alternate viewing system as a backup for the primary system.

12VAC5-481-290. Registration of Radiation Machine Facilities.

Each person having a radiation machine facility shall:

1. Apply for registration of such facility with the agency within 30 days following installation of equipment. Application for registration shall be completed on forms furnished by the agency and shall contain all the information required by the form and accompanying instructions. Registrations filed with the agency prior to September 20, 2006, shall remain in effect until a renewal notice is issued by the agency pursuant to 12VAC5-481-310 .

2. Designate on the application form an individual to be responsible for radiation protection.

3. Submit to the agency as part of any application for registration or renewal of registration one copy of each radiation survey or calibration report for which records are required to be maintained pursuant to 12VAC5-481-1591 A 12 c. Records submitted once need not be submitted again for renewal of registration.

4. Have an initial inspection by a private or state inspector no later than 30 days after the

registration of the equipment. Subsequent inspections shall be made periodically in accordance with other parts of these regulations or whenever the equipment is moved to a new location. The agency shall furnish a list of private inspectors.

12VAC5-481-300. Issuance of Registration Certificate.

A. Upon a determination that an applicant meets the requirements of this chapter and has paid the appropriate registration fee, the agency shall issue a registration certificate.

B. The agency may incorporate in the registration certificate at the time of issuance or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of radiation machines as he deems appropriate or necessary.

12VAC5-481-310. Renewal of Registration and Approval Not Implied.

A. Application for renewal of registration shall be filed in accordance with 12VAC5-481-290 .

B. In any case in which a registrant not less than 30 days prior to the expiration of his existing registration certificate has filed an application in proper form for renewal, such existing registration certificate shall not expire until the application status has been finally determined by the agency.

C. No person, in any advertisement, shall refer to the fact that he or his facility is registered with the agency pursuant to the provisions of 12VAC5-481-290 , and no person shall state or imply that any activity under such registration has been approved by the agency.

12VAC5-481-320. Expiration of Registration Certificate.

Except as provided by 12VAC5-481-310 B, each registration certificate shall expire at the end of the specified day in the month and year stated therein or upon notice issued to the registrant by the agency.

12VAC5-481-330. Report of Changes.

The registrant shall notify the agency in writing before making any change that would render the information contained in the application for registration and/or the notice of registration no longer accurate.

12VAC5-481-340. Private Inspector Qualifications.

Any person desiring designation as a private inspector for diagnostic x-ray, mammographic or therapeutic x-ray and teletherapy machines must be qualified by training and experience to perform inspections or calibrations according to the following criteria and must submit to the agency a statement on the appropriate form certifying his specific qualifications. In order to maintain designation as a private inspector, the individual must maintain satisfactory performance of work performed in that capacity. The agency shall disqualify any individual from this designation if the agency has determined that the individual has demonstrated unsatisfactory performance as a private inspector. The individual may request an informal

hearing.

A. Private inspector, diagnostic x-ray (except mammography). The person must have adequate knowledge, training and experience to measure ionizing radiation, evaluate safety techniques, and advise regarding radiation protection needs to assure compliance with Virginia Rules and Regulations for Ionizing Radiation as evidenced by all of the following:

1. Initial qualifications: evidenced by one or more of the following:

    a. Certification by one of the following: American Board of Radiology either in diagnostic or radiological physics, American Board of Health Physics in comprehensive practice, or the American Board of Medical Physics in diagnostic imaging physics.

    b. Bachelor's degree in one of the physical sciences or engineering and three years of full-time experience in radiation safety including at least one year in diagnostic x-ray safety. Advanced degrees in related areas may be substituted for experience on an equal time basis, except that no substitution shall be allowed for the required one year of experience in diagnostic x-ray safety.

    c. Those individuals listed as private inspectors immediately prior to September 20, 2006, shall be considered grandfathered.

2. Continuing qualifications:

    a. Continuing education. Private inspectors must participate in continuing education programs relating to diagnostic x-ray, either by teaching or completing at least 15 continuing education units (CMEs) every three years.

    b. Continuing experience. The private inspector must have inspected at least 10 diagnostic x-ray machines within the preceding 12 months.

3. Reestablishing qualifications. Private inspectors who fail to maintain the required continuing qualifications of this section may not perform the inspections without the supervision of a qualified private inspector. Before independently inspecting another facility, private inspectors must reestablish their qualifications, as follows:

    a. Private inspectors who fail to meet the continuing educational requirements of this section shall obtain a sufficient number of continuing education units to bring their total units up to five continuing education units during the preceding 12 months.

    b. Private inspectors who fail to meet the continuing experience requirement of this section shall complete a satisfactory inspection of a sufficient number of facilities and machines under the direct supervision of a private inspector who meets the qualifications of this section to bring the number to the required level.

B. Private inspector, therapeutic x-ray and teletherapy machines. The person must have adequate knowledge, training, and experience to calibrate a therapeutic x-ray machine or teletherapy machine, perform inspections and to establish procedures for (and review the results of) spot-check measurements as evidenced by all of the following:

1. Initial qualifications: evidenced by one or more of the following:

a. Be certified by the American Board of Radiology in:

(1) Therapeutic radiological physics or therapeutic medical physics;

(2) Roentgen-ray and gamma-ray physics;

(3) X-ray and radium physics;

(4) Radiological physics;

b. Be certified by the American Board of Medical Physics in Radiation Oncology Physics;

c. Be certified by the Canadian College of Medical Physics; or

d. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full time training in therapeutic radiological physics and also one year of full time work experience under the supervision of a radiation therapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 12VAC5-481-3400 A, 12VAC5-481-3420 P, 12VAC5-481-3420 Q, 12VAC5-481-3430 T, and 12VAC5-481-3430 U under the supervision of a radiation therapy physicist during the year of work experience.

Notwithstanding the provisions of 12VAC5-481-3390 D, certification pursuant to subdivisions B 1 a, b, or c of this section shall be required on or before July 1, 2007, for all persons currently qualifying as a radiation therapy physicist pursuant to subdivision B 1 d of this section.

2. Continuing qualifications.

a. Private inspectors must participate in continuing education programs relating to therapeutic x-ray and teletherapy machines, either by teaching or completing at least 15 continuing education units (CEUs) every three years.

b. The private inspector must have inspected at least one therapeutic x-ray or teletherapy facilities and at least one therapeutic x-ray or teletherapy machine within the preceding 12 months.

3. Reestablishing qualifications. Private inspectors who fail to maintain the required continuing qualifications of this section may not perform an inspection without the supervision of a qualified private inspector. Before independently inspecting another facility, private inspectors must reestablish their qualifications, as follows:

a. Private inspectors who fail to meet the continuing educational requirements of this section shall obtain a sufficient number of continuing education units to bring their total units up to five continuing education units during the preceding 12 months.

b. Private inspectors who fail to meet the continuing experience requirement of this section shall complete a satisfactory inspection of a sufficient number of facilities and

machines under the direct supervision of a private inspector who meets the qualifications of this section to bring the number to the required level.

C. Private inspector, mammography. The person must have adequate knowledge, training, and experience to inspect mammography x-ray machines and facilities. All mammography private inspector conducting inspections of mammography facilities and providing oversight of the facility quality assurance program must meet one of the following tracks, either through the initial master's degree of higher route or the alternative initial bachelor's degree route:

1. Initial qualifications:

Master Route:

a. Be certified by the American Board of Radiology (ABR) or the American Board of Medical Physics (ABMP) in:

(1) Diagnostic radiological physics;

(2) Radiological physics; or

(3) Diagnostic imaging physics;

b. A master's degree or higher in a physical science with at least 20 semester hours or equivalent of graduate or undergraduate physics; and

c. Twenty contact hours of mammography facility training; and

d. The experience of conducting inspections of at least one mammography facility and a total of at least 10 mammography units.

Bachelor Route (must have been qualified before April 28, 1999):

a. A bachelor's degree in a physical science with at least 10 semester hours or equivalent of college level physics;

b. Forty contact hours of documented specialized training in conducting inspections of mammography facilities; and

c. The experience of conducting inspections of at least one mammography facility and a total of at least 20 mammography units. The training and experience requirements must be met after fulfilling the degree requirement.

2. Continuing qualifications.

a. At all times after the third anniversary of completion of the initial requirements of this section, the private inspector shall have taught or completed at least 15 continuing education units in mammography during the preceding three years.

b. At all times after the first anniversary of the completion of the initial requirements of this section, the private inspector shall have inspected at least two mammography facilities and six machines in 24 months.

c. Before a private inspector may begin independently performing mammographic examinations using a new modality, that is, a modality other than one for which the physicist received training to qualify under this section, the inspector must receive at least eight hours of training in inspecting units with the new modality.

3. Reestablishing qualifications. Private inspectors who fail to maintain the required continuing qualifications of this section may not perform the mammography inspections without the supervision of a qualified private inspector. Before independently inspecting another facility, private inspectors must reestablish their qualifications as follows:

a. Private inspectors who fail to meet the continuing educational requirements of this section shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous three years.

b. Private inspectors who fail to meet the continuing experience requirement of this section shall complete a satisfactory inspection of three mammography facilities under the direct supervision of a private inspector who meets the qualifications of this section.

12VAC5-481-350. Assembler or Transfer Obligation.

A. Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation machines or upon significant service or modification thereof of any radiation machine (such as tube inserts, generators, or collimators) in this state shall notify the agency within 15 days of:

1. The name and address of persons who have received these machines;

2. The manufacturer, model, and serial number of each radiation machine transferred; however, in the case of diagnostic x-ray systems that contain certified components, a copy of the assembler's report (Form FDA 2579) prepared in compliance with the requirements of the Food and Drug Administration's Federal Diagnostic X-ray Standard (21 CFR 1020.30(d)) shall be submitted and shall suffice in lieu of any other report by the assembler; and

3. The date of transfer of each radiation machine.

B. No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and used shall meet the requirements of these regulations.

12VAC5-481-360. Reciprocal Recognition of Out-of-State Radiation Machines.

A. Whenever any radiation machine is to be brought into the state, for any temporary use, the person proposing to bring such machine into the state shall give written notice to the agency at least two working days before such machine is to be used in the state. The notice shall include:

1. The type of radiation machine;

2. The nature, duration, and scope of use;

3. The exact location(s) where the radiation machine is to be used; and

4. States in which this machine is registered.

B. If, for a specific case, the two-working-day period would impose an undue hardship on the person, upon application to the agency, permission to proceed sooner may be granted.

C. The person referred to in subsection A of this section shall:

1. Comply with all applicable regulations of the agency;

2. Supply the agency with such other information as the agency may reasonably request; and

3. Not operate within the state on a temporary basis in excess of 180 calendar days per year.

4. Supply the agency a copy of a medical physicist or private inspector report not less than one year old indicating the equipment is certified by another state.

12VAC5-481-370. Certification of X-Ray Systems.

A. Every owner or operator of an X-ray machine shall:

1. Have the machine certified by the agency within 60 days of the date of installation and thereafter according to the inspection schedule in Part VI (12VAC5-481-1580 et seq.) of this chapter; and

2. Have the machine inspected whenever the machine is moved to a new location or according to the schedule in Part VI (12VAC5-481-1580 et seq.) of this chapter, whichever occurs first, by a private or state inspector; and

3. Submit to the agency one copy of each inspection or calibration report for which records are required to be maintained pursuant to Part VI (12VAC5-481-1580 et seq.) of this chapter. If the inspection was performed by a state inspector and the inspection was not initiated by the agency pay the appropriate fee as established by the board.

B. Certification may be denied if any noncompliances are not corrected within 45 days from the date of inspection.

C. The agency shall issue a certificate when the data indicates the machine meets the board's standards. A copy of the certificate shall be displayed by the registrant in a conspicuous place in close proximity to the X-ray machine.

D. Certification may be denied if the machine does not meet the standards set forth in these regulations. If the certification is denied, the machine shall not be used for treatment, diagnosis, or evaluation of patients, whether human or animal, until the standards of the board have been met.

E. Final disposition of the machine, including electrical disconnection or storage, will be made within 90 days of agency review.

F. For facilities providing mammography services, the agency may conduct scheduled and random unannounced inspections, to ensure compliance with laws, regulations, or conditions specified by the board.

12VAC5-481-380. Purpose and Scope.

Part III. Licensing of Radioactive Material

Article 1. Purpose and Scope

A. This part, and Parts V (12VAC5-481-1170 et seq.), VII (12VAC5-481-1660 et seq.), XI (12VAC5-481-2330 et seq.), XIII (12VAC5-481-2950 et seq.), XIV (12VAC5-481-3140 et seq.) and XVI (12VAC5-481-3460 et seq.) of this chapter, provide for the licensing of radioactive material. No person shall receive, possess, use, transfer, own, or acquire radioactive material except as authorized pursuant to this part or Parts V (12VAC5-481-1170 et seq.), VII (12VAC5-481-1660 et seq.), XI (12VAC5-481-2330 et seq.), XII (12VAC5-481-2660 et seq.), XIII (12VAC5-481-2950 et seq.), XIV (12VAC5-481-3140 et seq.) and XVI (12VAC5-481-3460 et seq.) of this chapter, or as otherwise provided in these parts.

B. In addition to the requirements of this part, all licensees are subject to the requirements of Parts I (12VAC5-481-10 et seq.), IV (12VAC5-481-600 et seq.), X (12VAC5-481-2250 et seq.), and XIII (12VAC5-481-2950 et seq.) of this chapter. Furthermore, licensees engaged in industrial radiographic operations are subject to the requirements of Part V (12VAC5-481-1170 et seq.) of this chapter, licensees using radionuclides in the healing arts are subject to the requirements of Part VII (12VAC5-481-1660 et seq.) of this chapter, licensees engaged in irradiator operations are subject to the requirements of Part XII (12VAC5-481-2660 et seq.) of this chapter, and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of Part XIV (12VAC5-481-3140 et seq.) of this chapter.

12VAC5-481-390. Source Material.

Article 2. Exemptions from the Regulatory Requirements

A. Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from this part and the requirements for a license set forth in this chapter to the extent that they transport or store radioactive material in the regular course of the carriage for another or storage incident thereto.

B. Any person is exempt from Part III (12VAC5-481-380 et seq.) of this chapter to the extent that such person receives, possesses, uses, owns, transfers, or delivers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 0.05% of the mixture, compound, solution or alloy. The exemption contained in this chapter does not apply to Australian-obligated radioactive material, nor does it include byproduct materials as defined in 12VAC5-481-10 .

C. Any person is exempt from Part III (12VAC5-481-380 et seq.) of this chapter to the extent

that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

D. Any person is exempt from Parts III (12VAC5-481-380 et seq.), IV (12VAC5-481-600 et seq.), and X (12VAC5-481-2250 et seq.) of this chapter to the extent such person receives, possesses, uses, or transfers:

1. Any quantities of thorium contained in (i) incandescent gas mantles, (ii) vacuum tubes; (iii) welding rods; (iv) electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium; (v) germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than 2 grams of thorium; (vi) rare earth metals and compounds, mixtures, and products containing not more than 0.25% by weight thorium, uranium, or any combination of these; or (vii) personnel neutron dosimeters provided that each dosimeter does not contain more than 50 milligrams of thorium.

2. Source material contained in the following products:

a. Glaze ceramic tableware manufactured before August 27, 2013, provided that the glaze contains not more than 20% by weight source material;

b. Piezoelectric ceramic containing not more than 2.0% by weight source material;

c. Glassware containing not more than 2.0% by weight source material or for glassware manufactured before August 27, 2013, 10% by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction; or

d. Glass enamel or glass enamel frit containing not more than 10% by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983. (On July 25, 1983, the exemption of glass enamel or glass enamel frit was suspended. The exemption was eliminated on September 11, 1984.)

3. Photographic film, negatives, and prints containing uranium or thorium.

4. Any finished product or part fabricated of or containing tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4.0% by weight and that the exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part.

5. Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights provided that:

a. Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

b. Each counterweight is durably and legibly labeled or marked with the identification

of the manufacturer, and the statement: "Unauthorized Alterations Prohibited" (The requirements of this subdivision need not be met by counterweights manufactured prior to December 31, 1969, provided that such counterweights were manufactured under a specific license issued by the Atomic Energy Commission and were impressed with the legend required by 10 CFR 40.13(c)(5)(ii) in effect on June 30, 1969); and

c. The exemption contained in this subsection shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering.

6. Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

a. The shipping container is conspicuously and legibly impressed with the legend: "CAUTION—RADIOACTIVE SHIELDING—URANIUM", and

b. The uranium metal is encased in mild steel or equally fire-resistant metal of minimum wall thickness of 1/8 inch (3.2 mm).

7. Thorium or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than 10% by weight thorium or uranium or, for lenses manufactured before August 27, 2013, 30% by weight of thorium; and that the exemption contained in this paragraph does not authorize either:

a. The shaping, grinding, or polishing of such lens or mirror or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror; or

b. The receipt, possession, use, or transfer of uranium or thorium contained in contact lens, spectacles, or eyepieces in binoculars or other optical instruments.

8. Thorium contained in any finished aircraft engine part contained nickel-thoria alloy, provided that:

a. The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide); and

b. The thorium content in the nickel-thoria alloy does not exceed 4.0% by weight.

9. The exemptions in this subsection do not authorize the manufacture of any products described.

10. No person may initially transfer for sale or distribution a product containing source material to persons exempt under this subsection or equivalent regulations of the NRC or another agreement state, unless authorized by the NRC with a license issued under 10 CFR 40.52 to initially transfer such products for sale or distribution.

a. Persons initially distributing source material in products covered by the exemptions in this section before August 27, 2013, without specific authorization may continue such distribution for one year beyond this date. Initial distribution may also be

continued until the NRC takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than one year beyond this date.

b. Persons authorized to manufacture, process, or produce these materials or products containing source material, and persons who import finished products or parts, for sale or distribution shall be authorized by an NRC license issued under 10 CFR 40.52 for distribution only and are exempt from the requirements of 12VAC5-481-450 and Parts IV (12VAC5-481-600 et seq.) and X (12VAC5-481-2250 et seq.) of this chapter.

12VAC5-481-400. Radioactive Material Other Than Source Material.

A. Exempt concentrations.

1. Except as provided in subdivisions 3 and 4 of this subsection, any person is exempt from the requirements for a license set forth in this part to the extent that such person receives, possesses, uses, transfers, owns, or acquires products or materials containing radioactive material in concentrations not in excess of those listed in 12VAC5-481-3720 .

2. This subsection shall not be deemed to authorize the import of radioactive material or products containing radioactive material.

3. A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in this part to the extent that this person transfers radioactive material (i) contained in a product or material in concentrations not in excess of those specified in 12VAC5-481-3720 and (ii) introduced into the product or material by a licensee holding a specific license issued by the NRC expressly authorizing such introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by or application to a human being.

4. No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under this subsection or equivalent regulations by the NRC or another agreement state except in accordance with a license issued under 12VAC5-481-480 .

B. Exempt quantities.

1. Except as provided in subdivisions 3, 4, and 5 of this subsection, any person is exempt from the requirements of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities, each of which does not exceed the applicable quantity set forth in 12VAC5-481-3730 .

2. Any person who possesses radioactive material received or acquired before September 25, 1971, under the general license provided in 12VAC5-481-430 is exempt from the requirements for a license set forth in this part and from the regulations contained therein to the extent that this person possesses, uses, transfers, or owns radioactive material.

3. This subsection does not authorize for purposes of commercial distribution the

production, packaging, repackaging, or transfer of radioactive material or the incorporation of radioactive material into products intended for commercial distribution.

4. No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in 12VAC5-481-3730 , knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this part or equivalent regulations of the NRC or another agreement state, except in accordance with a license issued under 12VAC5-481-480 , which license states that the radioactive material may be transferred by the licensee to persons exempt under this part or the equivalent regulations of the NRC or another agreement state.

5. No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in 12VAC5-481-3730 , except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by this part.

C. Exempt items.

1. Except for persons who apply radioactive material to or persons who incorporate radioactive material into the following products, or persons who initially transfer for sale or distribution the following products containing radioactive material, any person is exempt from this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires the following products:

a. Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified quantities:

(1) 25 mCi (925 MBq) of tritium per timepiece;

(2) 5 mCi (185 MBq) of tritium per hand;

(3) 15 mCi (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial);

(4) 100 µCi (3.7 MBq) of promethium 147 per watch or 200 µCi (7.4 MBq) of promethium 147 per any other timepiece;

(5) 20 µCi (0.74 MBq) of promethium 147 per watch hand or 40 µCi (1.48 MBq) of promethium 147 per other timepiece hand;

(6) 60 µCi (2.22 MBq) of promethium 147 per watch dial or 120 µCi (4.44 MBq) of promethium 147 per other timepiece dial (bezels when used shall be considered as part of the dial);

(7) The levels of radiation from hands and dials containing promethium 147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(a) For wrist watches, 0.1 millirad per hour (1 microgray per hour) at 10 centimeters from any surface,

(b) For pocket watches, 0.1 millirad per hour (1 microgray per hour) at 1 centimeter

from any surface, or

(c) For any other timepiece, 0.2 millirad per hour (1 microgray per hour) at 10 centimeters from any surface; or

(8) 1 µCi (37 kBq) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

b. Other products including:

(1) Static elimination devices that contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 µCi (18.5 MBq) of polonium-210 per device;

(2) Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 µCi (18.5 MBq) of polonium-210 per device or of a total of not more than 50 mCi (1.85 GBq) of hydrogen-3 (tritium) per device; and

(3) Such devices authorized before October 23, 2012, for use under the general license then provided in 12VAC5-481-430 and equivalent regulations of the NRC or another agreement state and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the agency, the NRC, or another agreement state.

c. Balances of precision containing not more than 1 mCi (37 MBq) of tritium per balance or not more than 0.5 mCi (18.5 MBq) of tritium per balance part manufactured before December 17, 2007.

d. (Reserved.)

e. Marine compasses containing not more than 750 mCi (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 mCi (9.25 GBq) of tritium gas manufactured before December 17, 2007.

f. (Reserved.)

g. Ionization chamber smoke detectors containing not more than 1 µCi (37 kBq) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

h. Electron tubes (includes: spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents),providedthat each tube does not contain more than one of the following specified quantities:

(1) 150 mCi (5.55 GBq) of tritium per microwave receiver protector tube or 10 mCi (370 MBq) of tritium per any other electron tube;

(2) 1 µCi (37 kBq) of cobalt-60;

(3) 5 µCi (185 kBq) of nickel-63;

(4) 30 µCi (1.11 MBq) of krypton-85;

(5) 5 µCi (185 kBq) of cesium-137; or

(6) 30 µCi (1.11 MBq) of promethium-147; and

(7) Provided further that the levels of radiation dose from each electron tube containing radioactive material do not exceed 1 millirad per hour (10 microgray per hour) at 1 centimeter (0.39 inches) from any surface when measured through 7 milligrams per square centimeter of absorber.

i. Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:

(1) Each source contains no more than one exempt quantity set forth in 12VAC5-481-3730 , and

(2) Each instrument contains no more than 10 exempt quantities. For purposes of this subdivision, an instrument's source or sources may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in 12VAC5-481-3730 , provided that the sum of such fractions shall not exceed unity.

(3) For purposes of this subdivision, 0.05 µCi (1.85 kBq) of americium-241 is considered an exempt quantity under 12VAC5-481-3730 .

j. (Reserved.)

2. Any person who desires to apply radioactive material to, or to incorporate radioactive material into, the products exempted in subdivision 1 of this subsection, or who desires to initially transfer for sale or distribution such products containing radioactive material, should apply for a specific license pursuant to 12VAC5-481-480 C, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to subdivision 1 of this subsection.

D. Self-luminous products containing radioactive material.

1. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, or except as provided in subdivision 3 of this subsection, any person is exempt from the requirements for a license set forth in this part to the extent that such person receives, possesses, uses, transfers, own, or acquires tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific license issued pursuant to 12VAC5-481-480 D, which license authorizes the initial transfer of the product to persons who are exempt from regulatory requirements.

2. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie (3.7 kBq) of radium-226 acquired prior to September 1, 1980.

3. Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under subdivision 1 of this subsection should apply for a license and for a certificate of registration in accordance with 12VAC5-481-480 D.

4. The exemption in subdivision 1 of this subsection does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

E. Gas and aerosol detectors containing radioactive material.

1. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect health, safety, or property from fires and airborne hazards provided that the detectors containing radioactive material shall have been manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 12VAC5-481-480 E, which license authorizes use under this subsection. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by the NRC or another agreement state under provisions comparable to 12VAC5-481-480 C authorizing distribution to persons exempt from regulatory requirements.

2. Any person who desires to manufacture, process, or produce gas and aerosol detectors containing radioactive material, or to initially transfer such products for use under subdivision 1 of this subsection, should apply to the agency for a license in accordance with 12VAC5-481-480 C and for a certificate of registration with the NRC in accordance with 10 CFR 32.210.

3. Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an agreement state shall be considered exempt under subdivision 1 of this subsection, provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of 12VAC5-481-480 C.

4. Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by the NRC or another agreement state shall be considered exempt under subdivision 1 of this subsection, provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of 12VAC5-481-480 C.

F. Radioactive drug: Capsules containing carbon-14 urea for "in-vivo" diagnostic use for humans.

1. Except as provided in subdivision 2 of this subsection, any person is exempt from the requirements for a license set forth in this part, provided that such person receives, possess, uses, transfers, owns, or acquires capsules containing 1 µCi (37 kBq) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each for "in vivo" diagnostic use for humans.

2. Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to Part VII (12VAC5-481-1660 et seq.) of this chapter.

3. Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for a license under and a certification of registration in accordance with 12VAC5-481-480 I.

4. Nothing in this subsection relieves persons from complying with applicable U.S. Food and Drug Administration (FDA), other federal, and state requirements governing receipt, administration, and use of drugs.

G. Carriers. Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from this part to the extent that they transport special nuclear material in the regular course of carriage for another or storage incident thereto. This exemption does not apply to the storage in transit or transport of material by persons covered by a general license issued under 12VAC5-481-430 E.

H. Certain industrial devices.

1. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in § 32.1-229 of the Code of Virginia and in Parts III (12VAC5-481-380 et seq.), IV (12VAC5-481-600 et seq.), V (12VAC5-481-1170 et seq.), VII (12VAC5-481-1660 et seq.), X (12VAC5-481-2250 et seq.), XII (12VAC5-481-2660 et seq.), and XIV (12VAC5-481-3140 et seq.) of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the NRC under 10 CFR 32.30, which license authorizes the initial transfer of the device for use under this subsection. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

2. Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material for use under subdivision 1 of this subsection, should apply to the NRC for a license under 10 CFR 32.30 and for a certificate of registration in accordance with 10 CFR 32.210.

12VAC5-481-410. Types of Licenses.

Article 3. Licenses

A radioactive materials license will be one of the following:

1. A general license is provided by regulation, grants authority to a person for certain activities involving radioactive material, and is effective without the filing of an application with the agency or the issuance by the agency of licensing documents to the particular person; although, the filing of a certificate with the agency may be required by the particular general license. The general licensee is subject to all applicable parts of this chapter and any limitations of the general license.

2. A specific license requires the submission of an application to the agency and the issuance of a licensing document to a named person by the agency. A licensee is subject to all applicable parts of this chapter as well as any limitations specified in the licensing document.

12VAC5-481-420. General Licenses -- Source Material.

A. Small quantities of source material.

1. A general license is hereby issued authorizing commercial and industrial firms; research, educational, and medical institutions; and federal, state, and local government agencies to receive, possess, use, and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in the following forms and quantities:

a. No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (e.g. gaseous, liquid, powder, etc.) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material shall be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under this subdivision may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year; and

b. No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under this subdivision may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under this subdivision unless it is accounted for under the limits of subdivision 1 a of this subsection; or

c. No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under this paragraph; or

d. No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer

source material under this paragraph may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

2. Any person who receives, possesses, uses, or transfers source material in accordance with the general license in subdivision 1 of this subsection:

a. Is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the agency in a specific license.

b. Shall not abandon such source material. Source material may be disposed of as follows:

(1) A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, nondispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of this subdivision is exempt from the requirements to obtain a license under this part to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under this chapter; or

(2) In accordance with 12VAC5-481-910 .

c. Is subject to the provisions in 12VAC5-481-100 , 12VAC5-481-110 , 12VAC5-481-380 , 12VAC5-481-500 , 12VAC5-481-570 , 12VAC5-481-580 , and 12VAC5-481-1110 .

d. Shall not export such source material except in accordance with 10 CFR Part 110.

3. Any person who receives, possesses, uses, or transfers source material in accordance with subdivision 1 of this subsection shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the agency about such contamination and may consult with the agency as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in 12VAC5-481-1161 .

4. Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in subdivision 1 of this subsection is exempt from the provisions of Parts IV (12VAC5-481-600 et seq.) and X (12VAC5-481-2250 et seq.) of this chapter to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of 12VAC5-481-910 and 12VAC5-481-1161 to the extent necessary to meet the provisions of subdivisions 2 (b) and 3 of this subsection. However, this exemption does not apply to any person who also holds a specific license issued under this chapter.

5. No person may initially transfer or distribute source material to persons generally

licensed under subdivision 1 a or b of this subsection, or equivalent regulations of the NRC or another agreement state, unless authorized by a specific license issued in accordance with subdivision E of this subsection or equivalent provisions of the NRC or another agreement state. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample.

B. General license to receive title to source or radioactive material. A general license is hereby issued authorizing the receipt of title to source or radioactive material without regard to quantity. This general license does not authorize any person to receive, possess, deliver, use or transfer source or radioactive material.

C. Depleted uranium in industrial products and devices.

1. A general license is hereby issued to receive, acquire, possess, use or transfer, in accordance with the provisions of subdivisions 2, 3, 4, and 5 of this subsection, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

2. The general license in subdivision 1 of this subsection applies only to industrial products or devices that have been manufactured or initially transferred in accordance with a specific license issued by the agency, the NRC, or another agreement state, which authorizes manufacture of the products or devices for distribution to persons generally licensed.

3. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license in subdivision 1 of this subsection shall file a registration form with the agency by an appropriate method. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium and the agency shall be notified, in writing, within 30 days, of any change afterwards. The registrant shall furnish the following information and such other information as may be required:

a. Name and address of the registrant;

b. A statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in subdivision 1 of this subsection and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

c. Name, title, or both; address; and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in this subdivision.

4. A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established in subdivision 1 of this subsection:

a. Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium.

b. Shall not abandon such depleted uranium.

c. Shall transfer or dispose of such depleted uranium only by transfer in accordance with 12VAC5-481-570 . In the case where the transferee receives the depleted uranium pursuant to the general license established by subdivision 1 of this subsection, the transferor shall furnish the transferee a copy of this subsection and a copy of the appropriate agency form. In the case where the transferee receives the depleted uranium pursuant to a general license contained in a NRC or another agreement state's regulation equivalent to this subsection, the transferor shall furnish the transferee with a copy of this subsection and a copy of the appropriate agency form accompanied by a note explaining that use of the product or device is regulated by the NRC or agreement state under requirements substantially the same as those in this subsection.

d. Within 30 days of any transfer, shall report, in writing, to the agency the name and address of the person receiving the source material pursuant to such transfer.

5. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by subdivision 1 of this subsection is exempt from the requirements of Parts IV (12VAC5-481-600 et seq.) and X (12VAC5-481-2250 et seq.) of 12VAC5-481 with respect to the depleted uranium covered by that general license.

12VAC5-481-421. Requirements for License to Initially Transfer Source Material for Use under the Small Quantities of Source Material General License.

A. An application for a specific license to initially transfer source material for use under 12VAC5-481-420 A or equivalent regulations of the NRC or another agreement state will be approved if:

1. The applicant satisfies the general requirements specified in 12VAC5-481-450; and

2. The applicant submits adequate information on, and the agency approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.

B. Conditions of licenses to initially transfer source material for use under the small quantities of source material general license: quality control, labeling, safety instructions, and records and reports.

1. Each person licensed under subsection A of this section shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, "radioactive material."

2. Each person licensed under subsection A of this section shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

3. Each person licensed under subsection A of this section shall provide the information specified in this subdivision to each person to whom source material is transferred for use under 12VAC5-481-420 A or equivalent provisions of the NRC or another agreement state. This information shall be transferred before the source material is transferred for the first

time in each calendar year to the particular recipient. The required information includes:

a. A copy of 12VAC5-481-420 A and 12VAC5-481-570 , or relevant equivalent regulations of the NRC or another agreement state.

b. Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

4. Each person licensed under subsection A of this section shall report transfers as follows:

a. File a report with the Director, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555. The report shall include the following information:

(1) The name, address, and license number of the person who transferred the source material;

(2) For each general licensee under 10 CFR 40.22 or equivalent agreement state provisions to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name, position, or both and phone number, of the general licensee to whom the material was sent and the type, physical form, and quantity of source material transferred; and

(3) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

b. File a report with the agency and other agreement state agencies that identifies all persons operating under provisions equivalent to 12VAC5-481-420 A to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the agreement state to which the report is being made:

(1) The name, address, and license number of the person who transferred the source material;

(2) The name and address of the general licensee to whom source material was distributed; a responsible agent, by name, position, or both and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

(3) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the agreement state.

c. Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under 12VAC5-481-420 A or equivalent NRC and other agreement state provisions during the current period, a report shall be submitted to the agency indicating so. If no transfers have been made to general licensees of the NRC or in a particular agreement state during the

reporting period, this information shall be reported to the NRC or responsible agreement state agency upon request of the agency.

5. Each person licensed under subsection A of this section shall maintain all information that supports the reports required by this section concerning each transfer to a general licensee for a period of one year after the event is included in a report to the agency, the NRC, or another agreement state.

12VAC5-481-430. General Licenses -- Radioactive Material Other Than Source Material.

A. Certain devices and equipment.

1. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment that have been manufactured, tested, and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the agency or equivalent requirements by the NRC or another agreement state for use pursuant to 12VAC5-481-480 B or C.

a. Devices designed for use as static eliminators that contain, as a sealed source or sources, radioactive material consisting of a total not more than 500 µCi (18.5 MBq) of polonium-210 per device.

b. Devices designed for ionization of air that contain, as a sealed source or sources, radioactive material consisting of a total not more than 500 µCi (18.5 MBq) of polonium-210 per device or a total of not more than 50 mCi (1.85 GBq) of hydrogen-3 per device.

2. The general licenses provided in this subsection are subject to the general provisions of this subsection, the provisions of this part, and Parts IV (12VAC5-481-600 et seq.) and X (12VAC5-481-2250 et seq.) of this chapter unless indicated otherwise in the specific provision of the general license.

B. Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.

1. A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and federal, state, or local government agencies to acquire, receive, possess, use, or transfer, in accordance with the provisions of subdivisions 2, 3, 4, 5, and 6 of this subsection, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

2. The general license in subdivision 1 of this subsection applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in:

a. A specific license issued by the agency; or

b. An equivalent specific license issued by the NRC or another agreement state.

3. The devices shall have been received from one of the specific licensees described in this subsection or through a transfer made under subdivision 4 of this subsection.

4. Any person who owns, acquires, receives, possesses, uses, or transfers radioactive material in a device pursuant to the general license in subdivision 1 of this subsection:

a. Shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels.

b. Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; however:

(1) Devices containing only krypton need not be tested for leakage of radioactive material; and

(2) Devices containing only tritium or not more than 100 µCi (3.7 MBq) of other beta or gamma emitting material or 10 µCi (0.37 MBq) of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose.

c. Shall assure that the tests required by subdivision 4 of this subsection and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

(1) In accordance with the instructions provided by the labels; or

(2) By a person holding a specific license issued by the agency, the NRC, or another agreement state to perform such activities.

d. Shall maintain records showing compliance with the requirements of subdivision 4 of this subsection. The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installing, servicing, and removing from the installation radioactive material and its shielding or containment. The licensee shall retain these records as follows:

(1) Each record of a test for leakage or radioactive material required by subdivision 4 of this subsection shall be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of.

(2) Each record of a test of the on-off mechanism and indicator required by subdivision 4 of this subsection shall be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of.

(3) Each record that is required by subdivision 4 of this subsection shall be retained for

three years from the date of the recorded event or until the device is transferred or disposed of.

e. Shall immediately suspend operation of the device if there is a failure of, damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 µCi (185 Bq) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued by the agency, NRC, or another agreement state. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the agency. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 µCi (185 Bq) or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, shall be furnished to the agency within 30 days. Under these circumstances, the criteria set out in 12VAC5-481-1161 may be applicable, as determined by the agency on a case-by-case basis.

f. Shall not abandon the device containing radioactive material.

g. Shall not export the device containing radioactive material except in accordance with applicable provisions of this chapter.

h. Shall transfer or dispose of the device containing radioactive material only by export as provided by subdivision 4 g of this subsection, by transfer to another general licensee as authorized in subdivision 4 i of this subsection, or to a person authorized to receive the device by a specific license issued by the agency, the NRC, or another agreement state that authorizes waste collection or as otherwise approved under the following provisions of this subdivision B 4 h:

(1) Within 30 days after the transfer of a device to a specific licensee or export, furnish a report to the agency with the following information:

(a) The identification of the device by manufacturer's or initial transferor's name, model number, and serial number;

(b) The name, address, and license number of the person receiving the device (license number not applicable if exported); and

(c) The date of the transfer; and

(2) Obtain written agency approval before transferring the device to any other specific licensee not specifically identified in this subdivision; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval if the holder:

(a) Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(b) Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by subdivision 4 of this subsection) so that the device is labeled in compliance with 12VAC5-481-880; however, the manufacturer, model number, and serial number shall be retained;

(c) Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (e.g., as leak testing procedures); and

(d) Reports the transfer under subdivision 4 of this subsection.

i. Shall transfer the device to another general licensee only if:

(1) The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of this subsection, a copy of this part and 12VAC5-481-1090 and 12VAC5-481-1100 , and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the agency:

(a) The manufacturer's or initial transferor's name;

(b) The model number and the serial number of the device transferred;

(c) The transferee's name and mailing address for the location of use; and

(d) The name, title, and phone number of the responsible individual identified by the transferee in accordance with subdivision 4 l of this subsection to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

(2) The device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

j. Shall comply with the provisions of 12VAC5-481-1090 and 12VAC5-481-1100 for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of Parts IV (12VAC5-481-600 et seq.) and X (12VAC5-481-2250 et seq.) of this chapter.

k. Shall respond to written requests from the agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the agency a written justification for the request.

l. Shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

m. Shall annually register devices containing at least 10 mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, 1 mCi (37 MBq) of cobalt-60, 0.1 mCi (3.7 MBq) of radium-226, or 1 mCi (37 MBq) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use represents a separate general licensee and requires a separate registration and fee. The registration fee will be $50 per device.

(1) The registration information shall be submitted to the agency within 30 days of the requested date for registration or as otherwise indicated in the request, and at a minimum include the following information and any other information specifically requested by the agency:

(a) Name and mailing address of the general licensee.

(b) Information about each device, including the manufacturer or initial transferor, model number, serial number, the radioisotope and activity (as indicated on the label).

(c) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under subdivision 4 l of this subsection.

(d) Address or location at which the device or devices are used or stored. For portable devices, the address of the primary place of storage.

(e) Certification by the responsible representative of the general licensee that the information concerning the device or devices has been verified through a physical inventory and checking of label information.

(f) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

(2) A general licensee holding devices meeting the criteria of subdivision 4 m of this subsection is subject to the bankruptcy notification requirement in 12VAC5-481-500 E.

n. Shall report changes to the mailing address for the location of use, including change in name of general licensee, to the agency within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage of the device.

o. May not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter shall be locked in the closed position. The testing required by subdivision 4 of this subsection need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person and have not been tested within the required test interval they shall be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

5. The general license in this subsection does not authorize the manufacture or import of

devices containing radioactive material.

6. The general license provided in this subsection is subject to the provisions of this part and Parts IV (12VAC5-481-600 et seq.) and X (12VAC5-481-2250 et seq.) of this chapter unless indicated otherwise in the specific provision of the general license.

C. The general license provided in 12VAC5-481-420 B is subject to the provisions of 12VAC5-481-100 through 12VAC5-481-210 , 12VAC5-481-500 , 12VAC5-481-570 , 12VAC5-481-580 and Part XIII (12VAC5-481-2950 et seq.) of this chapter.

D. Luminous safety devices for use in aircraft. In addition, this general license is subject to the provisions of 12VAC5-481-100 through 12VAC5-481-210 , 12VAC5-481-500 , 12VAC5-481-570 , 12VAC5-481-580 , and Part XIII (12VAC5-481-2950 et seq.) of this chapter.

1. A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided each device contains not more than 10 Ci (370 GBq) of tritium or 300 mCi (11.1 GBq) of promethium-147 and that each device has been manufactured, assembled, or initially transferred in accordance with a license issued under the provisions of 12VAC5-481-480 D or manufactured or assembled in accordance with a specific license issued by the NRC or another agreement state that authorizes manufacture or assembly of the device for distribution to persons generally licensed the agency or NRC.

2. Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in this subdivision are exempt from the requirements of Parts IV (12VAC5-481-600 et seq.) and X (12VAC5-481-2250 et seq.) of this chapter, except that they shall comply with the provisions of 12VAC5-481-1090 and 12VAC5-481-1100 .

3. This general license does not authorize the manufacture, assembly, repair, or import of luminous safety devices containing tritium or promethium-147.

4. This general license does not authorize the export of luminous safety devices containing tritium or promethium-147.

5. This general license does not authorize the ownership, receipt, acquisition, possession, or use of promethium-147 contained in instrument dials.

6. The general license provided in this subsection is subject to the general provisions of this subsection, the provisions of this part, and Parts IV (12VAC5-481-600 et seq.) and X (12VAC5-481-2250 et seq.) of this chapter unless indicated otherwise in the specific provision of the general license.

E. General license to own radioactive material.

1. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provision of this subsection, a general license under this subsection is not authorized to manufacture, produce, transfer, receive, possess, use, import, or export radioactive material, except as authorized in a specific license.

2. A general license is hereby issued to receive title to and own special nuclear material

without regard to quantity. Notwithstanding any other provision of this subsection, a general license under this subsection is not authorized to acquire, deliver, receive, possess, use, transfer, import, or export special nuclear material, except as authorized in a specific license.

3. The general license provided in this subsection is subject to the general provisions of this subsection, the provisions of this part, and Parts IV (12VAC5-481-600 et seq.) and X (12VAC5-481-2250 et seq.) of this chapter unless indicated otherwise in the specific provision of the general license.

F. Calibration and reference sources.

1. A general license is hereby issued to own, receive, acquire, possess, use, and transfer americium-241 in the form of calibration or reference sources in accordance with the provisions of subdivisions 4 and 5 of this subsection to any person who holds a specific license issued by the agency that authorizes receipt, possession, use, and transfer of radioactive material.

2. A general license is hereby issued to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of subdivisions 4 and 5 of this subsection to any person who holds a specific license issued by the agency that authorizes him to receive, possess, use, and transfer radioactive material.

3. A general license is hereby issued to own, receive, possess, use, and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of subdivisions 4 and 5 of this subsection to any person who holds a specific license issued by the agency which authorizes him to receive, possess, use, and transfer radioactive material.

4. The general licenses in subdivisions 1 through 3 of this subsection apply only to calibration or reference sources that have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the NRC pursuant to 10 CFR 32.57 or 10 CFR 70.39, or that have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the agency or another agreement state pursuant to licensing requirements equivalent to those contained in 10 CFR 32.57 or 10 CFR Part 70.39.

5. The general licenses provided in subdivisions 1 through 3 of this subsection are subject to the provisions of 12VAC5-481-100 through 12VAC5-481-210 , 12VAC5-481-500 , 12VAC5-481-570 , 12VAC5-481-580 and Parts IV (12VAC5-481-600 et seq.); X (12VAC5-481-2250 et seq.); and XIII (12VAC5-481-2950 et seq.) of this chapter. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:

a. Shall not possess at any one time, at any one location of storage or use, more than 5 µCi (185 kBq) of americium-241, plutonium, or radium-226 in such sources;

b. Shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label that includes one of the following statements, as

appropriate, or a substantially similar statement that contains the information called for in one of the following statements, as appropriate:

(1) The receipt, possession, use, and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the Nuclear Regulatory Commission or of a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL

THIS SOURCE CONTAINS (AMERICIUM-241).

(PLUTONIUM) (Showing only the name of the appropriate material.)

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____Name of manufacturer or importer

(2) The receipt, possession, use, and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of a licensing state. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL

THIS SOURCE CONTAINS RADIUM-226.

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____Name of manufacturer or importer

c. Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the agency, the NRC, or another agreement state to receive the source;

d. Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 that might otherwise escape during storage; and

e. Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

6. These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

7. This general license does not authorize the export of calibration or reference sources containing americium-241, plutonium, or radium-226.

8. The general license provided in this subsection is subject to the general provisions of this subsection and Parts IV (12VAC5-481-600 et seq.) and X (12VAC5-481-2250 et seq.) of this chapter unless indicated otherwise in the specific provision of the general license.

G. General license for use of radioactive material for certain in vitro clinical or laboratory testing.

1. A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital to receive, acquire, possess, transfer, or use for any of the following stated tests in accordance with the provisions of this subsection the following radioactive materials in prepackaged units for use in-vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

a. Iodine-125, in units not exceeding 10 µCi (370 kBq) each.

b. Iodine-131, in units not exceeding 10 µCi (370 kBq) each.

c. Carbon-14, in units not exceeding 10 µCi (370 kBq) each.

d. Hydrogen-3 (tritium), in units not exceeding 50 µCi (1.85 MBq) each.

e. Iron-59, in units not exceeding 20 µCi (740 kBq) each.

f. Selenium-75, in units not exceeding 10 µCi (370 kBq) each.

g. Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 µCi (1.85 kBq) of iodine-129 and 0.005 µCi (185 Bq) of americium-241 each.

h. Cobalt-57, in units not exceeding 10 µCi (0.37 MBq) each.

2. A person shall not receive, acquire, possess, use, or transfer radioactive material under the general license established by subdivision 1 of this subsection unless that person:

a. Has filed the In Vitro Testing GL form with the agency and has received from the agency a validated copy with a registration number assigned. The physician, veterinarian, clinical laboratory, or hospital shall furnish the name and address of the physician, veterinarian, clinical laboratory, or hospital; the location of use; and a statement that the physician, veterinarian, clinical laboratory, or hospital has appropriate radiation measuring instruments to carry out in-vitro clinical or laboratory tests with radioactive material as authorized by this subsection and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material; or

b. Has a license that authorizes the medical use of radioactive material that was issued under Part VII (12VAC5-481-1660 et seq.) of 12VAC5-481 .

3. A person who receives, acquires, possesses, or uses radioactive material pursuant to the general license established by subdivision 1 of this subsection shall comply with the following:

a. The general licensee shall not possess at any one time under the general license in subdivision 1 of this subsection at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, cobalt-57, or iron-59 in excess of 200 µCi (7.4 MBq).

b. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

c. The general licensee shall use the radioactive material only for the uses authorized by subdivision 1 of this subsection.

d. The general licensee shall not transfer the radioactive material except by transfer to a person authorized to receive it by a license pursuant to this chapter, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

e. The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in this subsection as required by 12VAC5-481-910 .

4. The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to subdivision 1 of this subsection:

a. Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under the provisions of 12VAC5-481-480 G or in accordance with the provisions of a specific license issued by the NRC or another agreement state that authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59, cobalt-57, or Mock Iodine-125 for distribution to persons generally licensed, and

b. Unless the following statement, or a substantially similar statement that contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure that accompanies the package:

"This radioactive material may be received, acquired, possessed, and used only by physicians or veterinarians in the practice of veterinary medicine, clinical laboratories, or hospitals and only for in-vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

(Name of Manufacturer)"

5. The registrant possessing or using radioactive materials under the general license of subdivision 1 of this subsection shall report in writing to the agency, any changes in the information furnished to the agency in the Registration Certificate – In Vitro Testing With Radioactive Material Under General License within 30 days after the effective date of such change.

6. Any person using radioactive material pursuant to the general license of subdivision 1 of this subsection is exempt from the requirements of Parts IV (12VAC5-481-600 et seq.) and X (12VAC5-481-2250 et seq.) of this chapter with respect to radioactive materials covered by that general license, except that such persons using the Mock Iodine-125 described in subdivision 1 of this subsection shall comply with the provisions of 12VAC5-481-910 , 12VAC5-481-1090 , and 12VAC5-481-1100 .

7. The general license provided in this subsection is subject to the provisions of this part and Parts IV (12VAC5-481-600 et seq.) and X (12VAC5-481-2250 et seq.) of this chapter unless indicated otherwise in the specific provision of the general license.

H. Strontium-90 in ice detection devices.

1. A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 µCi (1.85 MBq) of strontium-90 and each device has been manufactured or initially transferred in accordance with the specifications contained in a license issued pursuant to 12VAC5-481-480 H or in accordance with the specifications contained in a specific license issued to the manufacturer by the NRC or another agreement state authorizing manufacture of the ice detection devices for distribution to persons generally licensed.

2. Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in subdivision 1 of this subsection:

a. Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating, to the device, (i) discontinue use of the device until it has been inspected, tested for leakage, and repaired by a person holding a specific license pursuant to this part or Part IV (12VAC5-481-600 et seq.) of this chapter, or from the NRC or another agreement state to manufacture or service such devices; or (ii) dispose of the device pursuant to the provisions of 12VAC5-481-910 .

b. Shall assure that all labels affixed to the device at the time of receipt, and that bear a statement that prohibits removal of the labels, are maintained thereon.

c. Are exempt from the requirements of Parts IV (12VAC5-481-600 et seq.) and X (12VAC5-481-2250 et seq.) of this chapter except that such persons shall comply with the provisions of 12VAC5-481-910 , 12VAC5-481-1090 , and 12VAC5-481-1100 .

3. The general license does not authorize the manufacture, assembly, disassembly, repair, or import of strontium-90 in ice detection devices.

4. The general license provided in this subsection is subject to the provisions of this part, and Parts IV (12VAC5-481-600 et seq.) and X (12VAC5-481-2250 et seq.) of this chapter unless indicated otherwise in the specific provision of the general license.

I. Certain items and self-luminous products containing radium-226.

1. A general license is hereby issued to any person to acquire, receive, possess, use, or transfer in accordance with the provisions of the following subdivisions radium-226 contained in the following products manufactured prior to November 30, 2007.

a. Antiquities originally intended for use by the general public. For the purposes of this subsection, "antiquities" mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

b. Intact timepieces containing greater than 1 µCi (0.037 MBq), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

c. Luminous items installed in air, marine, or land vehicles.

d. All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.

e. Small radium sources containing no more than 1 µCi (0.037 MBq) of radium-226. For the purposes of this subsection, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the NRC.

2. Persons who acquire, receive, possess, use, or transfer radioactive material under the general license issued in subdivision 1 of this subsection are exempt from the provisions of Parts IV (12VAC5-481-600 et seq.) and X (12VAC5-481-2250 et seq.) of this chapter, as well as 12VAC5-481-1090 and 12VAC5-481-1100 , to the extent that the receipt, possession, use, or transfer of radioactive material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed.

3. Any person who acquires, receives, possesses, uses, or transfers radioactive material in accordance with the general license in subdivision 1 of this subsection:

a. Shall notify the agency should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event and the remedial action taken shall be furnished to the agency within 30 days.

b. Shall not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to 12VAC5-481-971 or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the agency.

c. Shall not export products containing radium-226 except in accordance with this chapter.

d. Shall dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any federal or state solid or hazardous waste law, including the Solid Waste Disposal Act (42 USC § 6901 et seq.), as authorized under the Energy Policy Act of 2005 (42 USC § 15801 et seq.), by transfer to a person authorized to receive radium-226 by a specific license issued under this part or equivalent regulations of the NRC or another agreement state, or as otherwise approved by the agency.

e. Shall respond to written requests from the agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time

specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the agency a written justification for the request.

4. The general license in subdivision 1 of this subsection does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

5. The general license provided in this subsection is subject to the general provisions of this subsection, the provisions of this part, and Parts IV (12VAC5-481-600 et seq.) and X (12VAC5-481-2250 et seq.) of this chapter unless indicated otherwise in the specific provision of the general license.

J. General license to install and service generally licensed devices. Any person who holds a specific license issued by the NRC or another agreement state authorizing the holder to manufacture, install, or service a device described in this subsection, is hereby granted a general license to install and perform nonradiological service (i.e., leak testing, surveys, routine maintenance) of the devices, provided that:

1. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the NRC or another agreement state; and

2. Such person assures that any labels required to be affixed to the device under regulations of the NRC or another agreement state licensing the manufacture of the device bear a statement that removal of the label is prohibited.

12VAC5-481-440. Filing Application for Specific Licenses.

Article 4. Specific Licenses

A. Applications for specific licenses shall be filed on a form prescribed by the agency.

B. The agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

C. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

D. An application for a license may include a request for a license authorizing one or more activities.

E. Applications and documents submitted to the agency may be made available for public inspection in accordance with the Virginia Freedom of Information Act (§ 2.2-3700 et seq. of the Code of Virginia). The agency may withhold records in accordance with specific exemptions in the Virginia Freedom of Information Act or as otherwise specified by law.

F. An application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source shall either:

1. Identify the source or device by manufacturer and model number as registered with the NRC under 10 CFR 32.210 or an agreement state under equivalent regulations;

2. Contain the information in 10 CFR 32.210(c);

3. For sources or devices containing radioactive material manufactured prior to October 23, 2012, that are not registered with the NRC under 10 CFR 32.210 or with an agreement state, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c), the applicant shall provide:

a. All available information identified in 10 CFR 32.210(c) concerning the source, and, if applicable, the device; and

b. Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information shall include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test;

4. For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR 32.210(g)(1), the applicant may supply only the manufacturer, model number, and radionuclide and quantity; or

5. If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used in lieu of identifying each sealed source and device.

G. Each application to possess radioactive material in unsealed form, on a foil or plated source, or sealed in glass in excess of the quantities in 12VAC5-481-3740 shall contain one of the following:

1. An evaluation showing that the projected dose to a person offsite due to a release of radioactive material would not exceed 0.01 Sv (1 rem) total effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or

2. An emergency plan, reviewed and commented on by offsite response organizations expected to respond in the event of an accident that contains the following information:

a. Facility description. A brief description of the licensee or applicant's facility and surroundings.

b. Types of accidents. An identification of each type of radioactive materials accident for which actions by licensee staff or offsite response organizations will be needed to protect members of the public.

c. Classification of accidents. A method for classifying and declaring an accident as alert or

site area emergency.

d. Detection of accidents. Identification of the means for detecting each type of alert or site area emergency in a timely manner.

e. Mitigation of consequences. A brief description of the means and equipment that are available for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

f. Assessment of releases. A brief description of the methods and equipment available to assess releases of radioactive material.

g. Responsibilities. A brief description of the responsibilities of the licensee or applicant's personnel who will respond if an accident occurs, including identification of personnel responsible for promptly notifying offsite response organizations, including the agency.

h. Plan maintenance. A brief description of the positions assigned and methods to develop, maintain and update the plan.

i. A list of offsite response organizations, description of their responsibilities and anticipated actions, and copy of formal commitments, if any.

j. Notification and coordination. A brief description of the means to promptly notify the offsite response organizations and request offsite assistance including medical assistance for the treatment of contaminated injured onsite workers. The notification and coordination shall include alternate provisions in case key personnel, parts of the facility, or some equipment are unavailable. The licensee shall also commit to notify the agency immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

k. Information to be communicated. A brief description of the types of information on facility status, radioactive releases and recommended protective actions, if necessary, to be given to offsite response organizations and the agency. A licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensees emergency plan before submitting it to the agency. A licensee shall provide any comments received within the 60 days to the agency with the emergency plan.

l. Training. A brief description of the frequency, performance objectives and plan for training that the licensee or applicant will provide workers on how to respond to an emergency, including any special instructions and orientation tours that the licensee or applicant will offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific hazards and emergency procedures. The training shall also prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of drills, exercises and team training for such scenarios.

m. Drills and exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated

emergencies. The licensee or applicant shall invite offsite response organizations to participate in biennial exercises. The exercises shall use accident scenarios postulated as the most probable for the specific site and the scenarios may not be known to most exercise participants. Critiques of exercises shall evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel and overall effectiveness of the response. Deficiencies found by the critiques shall be corrected.

n. Safe condition. A brief description of the means of restoring the facility and surroundings to a safe condition after an accident.

o. Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-To-Know Act of 1986, Title III, P.L. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

H. An application from a medical facility or educational institution to produce PET radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under Part VII (12VAC5-481-1660 et seq.) of this chapter shall include:

1. A request for authorization for the production of PET radionuclides or evidence of an existing license issued under Part III (12VAC5-481-380 et seq.) of this chapter for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

2. Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 12VAC5-481-480 I.

3. Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an ANP as specified in 12VAC5-481-480 I 2.

4. Information identified in 12VAC5-481-480 I 1 c on the PET drugs to be noncommercially transferred to members of its consortium.

I. Manufacture, preparation, or transfer for commercial distribution of drugs containing radioactive material for medical use under Part VII (12VAC5-481-1660 et seq.).

1. An application for a specific license to manufacture, prepare, or transfer for commercial distribution drugs containing radioactive material for use by persons authorized pursuant to Part VII (12VAC5-481-1660 et seq.) will be approved if:

a. The applicant satisfies the general requirements specified in 12VAC5-481-450 ;

b. The applicant submits evidence that the applicant is at least one of the following:

(1) Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;

(2) Registered or licensed with a state agency as a drug manufacturer;

(3) Licensed as a pharmacy by the Virginia Board of Pharmacy;

(4) Operating as a nuclear pharmacy within a federal medical institution; or

(5) A PET drug production facility registered with a state agency.

c. The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

d. The applicant satisfies the following labeling requirements:

(1) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol as described in 12VAC5-481-850 and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted.

(2) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol as described in 12VAC5-481-850 and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

2. A licensee authorized to manufacture, prepare or transfer for commercial distribution radioactive drugs shall ensure that any individual preparing the drugs is one of the following:

a. An authorized nuclear pharmacist (ANP) as defined in 12VAC5-481-10 ;

b. An individual that meets the requirements specified in 12VAC5-481-1770 and 12VAC5-481-1790 , and the licensee has received an approved license amendment identifying this individual as an ANP;

c. A pharmacist, as defined in 12VAC5-481-10 , designated as an ANP if:

(1) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material; and

(2) The individual practiced at a pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC; or

d. An individual under the supervision of an ANP as specified in 12VAC5-481-1710 .

3. Shall provide to the agency no later than 30 days after the date that the licensee allows, under subdivision 2 a or c of this subsection, the individual to work as an ANP:

a. The individual's certification by a specialty board whose certification process has

been recognized by the NRC with the written attestation signed by a preceptor as required by 12VAC5-481-1770;

b. An NRC or another agreement state license;

c. NRC master materials licensee permit;

d. The permit issued by a licensee or NRC master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

e. Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

f. The Virginia Board of Pharmacy's license.

4. A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha, beta, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

a. Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

b. Check each instrument for constancy and proper operation at the beginning of each day of use.

5. Nothing in this subsection relieves the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

6. Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/ryubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination in accordance with 12VAC5-481-1930 . The licensee shall record the results of each test and retain each record for three years after the record is made.

12VAC5-481-450. General Requirements for the Issuance of Specific Licenses.

A. A license application will be approved if the agency determines that:

1. The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these regulations in such a manner as to minimize danger to public health and safety or property;

2. The applicant's proposed equipment, facilities, and procedures are adequate to minimize

danger to public health and safety or property;

3. The issuance of the license will not be inimical to the health and safety of the public;

4. The applicant has described in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste;

5. Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with this chapter; and

6.The applicant satisfies any applicable special requirements in 12VAC5-481-460 , 12VAC5-481-470 , 12VAC5-481-480 , or Part V (12VAC5-481-1170 et seq.), Part VII (12VAC5-481-1660 et seq.), Part XI (12VAC5-481-2330 et seq.), Part XII (12VAC5-481-2660 et seq.), Part XIV (12VAC5-481-3140 et seq.), or Part XVI (12VAC5-281-3460 et seq.) of this chapter.

B. Environmental report, commencement of construction. In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, or for the conduct of any other activity that the agency determines will significantly affect the quality of the environment, the agency, before commencement of construction of the plant or facility in which the activity will be conducted, has concluded, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in this subsection the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

C. Financial assurance and records for decommissioning.

1. A person applying for a specific license authorizing the possession and use of unsealed radioactive material shall submit a decommissioning funding plan as described in subdivision 6 of this subsection with the license application for any of the following types of materials:

a. Unsealed radioactive material with a half-life greater than 120 days and in quantities greater than 10^5 times the applicable quantities listed in 12VAC5-481-3750 .

b. Unsealed radioactive material involving a combination of isotopes with R divided by 10^5 being greater than one, where R is defined as the sum of the ratios of the quantity of each isotope to the applicable value in 12VAC5-481-3750 .

2. A person applying for a specific license authorizing the possession and use of radioactive material not covered by subdivision 1 of this subsection with a half-life greater than 120 days and in quantities specified in subdivision 5 of this subsection shall do either of the following:

a. Submit a decommissioning funding plan as described in subdivision 6 of this subsection.

b. Submit a written certification, signed by the chief financial officer or other individual designated by management to represent the licensee, that financial assurance has been provided in the amount prescribed in subdivision 5 of this subsection using one of the methods described in subdivision 6 of this subsection and a signed original of the financial instrument obtained to satisfy the requirements of subdivision 7 of this subsection. The written certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued by the agency but before receipt of radioactive material by the applicant. If the applicant defers execution of the financial instrument until after the license has been issued, the applicant shall submit to the agency a signed original of the financial instrument obtained before receipt of licensed material.

3. The following are exempt from the requirements of this subsection:

a. A state, local or other government agency, except for a government agency licensed to handle or process radioactive waste.

b. A person authorized to possess only radioactive materials with a half-life of 65 days or less.

c. Other persons exempted by the agency based on a review of the license application.

4. Implementation.

a. A person who possesses a specific license authorizing the possession and use of radioactive material issued on or after the effective date as stated in 12VAC5-481-160 that is of a type described in subdivision 1 of this subsection, shall provide financial assurance for decommissioning under this section.

b. A person who possesses a specific license issued before the effective date as stated in 12VAC5-481-160 shall do one of the following:

(1) For a license authorizing the use of radioactive material meeting the criteria of subdivision 1 of this subsection, submit a decommissioning funding plan as described in subdivision 6 of this subsection and a certification of financial assurance for at least $1,125,000, under the criteria in subdivision 5 of this subsection, with any application for license renewal.

(2) For a license authorizing the use of radioactive material meeting the criteria of subdivision 2 of this subsection, submit a decommissioning funding plan as described in subdivision 6 of this subsection or a certification of financial assurance for

decommissioning according to the criteria of subdivision 5 of this subsection with any application for license renewal.

c. The term of the financial assurance shall be from the issuance or renewal of the license until the agency terminates the license.

d. A licensee's financial assurance arrangements may be reviewed annually by the agency to recognize any increases or decreases resulting from inflation or deflation, changes in engineering plans, activities performed or any other condition affecting costs for decommissioning to ensure that sufficient funding is available to cover liability that remains until license termination.

5. Required amounts for financial assurance.

a. A licensee shall provide the following minimum amounts of financial assurance for decommissioning, unless otherwise specified by the agency:

(1) $1,125,000 if the quantity of material is greater than 10^4 but less than or equal to 10^5 times the applicable quantities of 12VAC5-481-3750 in unsealed form. For a combination of isotopes, R divided by 10^4 is greater than one but R divided by 10^5 is less than or equal to one.

(2) $225,000 if the quantity of material is greater than 10^3 but less than or equal to 10^4 times the applicable quantities of 12VAC5-481-3750 in unsealed form. For a combination of isotopes, R divided by 10^3 is greater than one but R divided by 10^4 is less than or equal to one.

(3) $113,000 if the quantity of material is greater than 10^{10} times the applicable quantities of 12VAC5-481-3750 in sealed sources or plated foils. For a combination of isotopes, R divided by 10^{10} is greater than one.

b. The agency may eliminate, reduce or raise the required amount of financial assurance under subdivision 5 a of this subsection for an individual applicant or licensee based on the cost estimate for decommissioning included in the decommissioning funding plan required under subdivision 6 a of this subsection.

6. Each decommissioning funding plan (DFP) shall be submitted for review and approval by the agency.

a. The DFP shall include a detailed cost estimate for decommissioning, in an amount reflecting:

(1) The cost of an independent contractor to perform all decommissioning activities;

(2) The cost of meeting the criteria for unrestricted use in 12VAC5-481-1161 B provided that if the applicant or licensee can demonstrate its ability to meet the provisions of 12VAC5-481-1161 C, the cost estimate may be based on meeting the criteria in 12VAC5-481-1161 C;

(3) The volume of onsite subsurface material containing residual radioactivity that will

require remediation to meet the criteria for license termination; and

(4) An adequate contingency factor;

b. The DFP shall include identification of and justification for using the key assumptions contained in the decommissioning cost estimate (DCE);

c. The DFP shall include a description of the method of assuring funds for decommissioning from subdivision 7 of this subsection, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

d. The DFP shall include a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning;

e. The DFP shall include a signed original of the financial instrument obtained to satisfy the requirements of subdivision 7 of this subsection (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning); and

f. The DFP shall (i) be submitted with license renewal and at intervals not to exceed three years and (ii) contain adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this cannot be done until the updated decommissioning funding plan is approved. The DFP shall update the information submitted with the original or prior approved plan and shall specifically consider the effect of the following events on decommissioning costs:

(1) Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

(2) Waste inventory increasing above the amount previously estimated;

(3) Waste disposal costs increasing above the amount previously estimated;

(4) Facility modifications;

(5) Changes in authorized possession limits;

(6) Actual remediation costs that exceed the previous cost estimate;

(7) Onsite disposal; and

(8) Use of a settling pond.

7. A licensee may use any of the following methods to provide financial assurance for decommissioning:

a. Prepayment. Prepayment is the deposit prior to operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets in an amount sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit or deposit of

government securities. Funds placed into a trust segregated from the licensee's assets and outside the licensee's administrative control, and in which the adequacy of the trust funds is to be assessed based on an assumed annual 1.0% real rate of return on investment.

b. Surety method, insurance or other guarantee. Payment of future decommissioning costs shall be guaranteed by a surety method, insurance or other guarantee. A surety method may be in the form of a surety bond, letter of credit or line of credit. Self insurance, or any method that essentially constitutes self-insurance, may not be used as a method of providing financial assurance. Any surety method or insurance used to provide financial assurance for decommissioning shall meet all of the following criteria:

(1) The surety method or insurance shall be open-ended or, if written for a specified term, renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the agency, the beneficiary and the licensee of its intention not to renew. The surety method or insurance shall also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the agency within 30 days after receipt of notification of cancellation.

(2) The surety method or insurance shall be payable to a trust established for decommissioning costs. The agency shall approve the trustee and the trust.

(3) The surety method or insurance shall remain in effect until the agency terminates the license.

c. External sinking fund. An external sinking fund may be used in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit or deposit of government securities. The surety or insurance provisions shall meet the requirements of subdivision 7 b of this subsection.

d. Statement of intent. A state or local government licensee exempt under subdivision 3 of this subsection shall submit a written statement of intent containing a cost estimate for decommissioning or an amount based on subdivision 5 of this subsection. The cost estimate shall indicate that funds for decommissioning will be obtained when necessary.

8. A licensee shall keep the following records of information related to decommissioning of a facility in an identified location until the site is released for unrestricted use:

a. Records of spills or other unusual occurrences involving the spread of radioactive contamination in and around the facility, equipment or site. The records may be limited to instances where contamination remains after any cleanup procedures or when there is reasonable likelihood that radioactive contaminants may have spread to inaccessible areas or into porous materials such as concrete. The records shall include any known information on identification of involved nuclides, quantities, forms and

concentrations.

b. As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used or stored, and of locations of possible inaccessible contamination such as buried pipes that may contain radioactive contaminants. If required drawings are referenced, each relevant document does not need to be indexed individually. If drawings are not available, a licensee shall substitute appropriate records of available information concerning the areas and locations of inaccessible contamination.

Note: As-built architectural and engineering drawings need to reflect the final details of the structures and equipment as they were constructed.

c. Except for areas containing only sealed sources that have not leaked or where no contamination remains after a leak, or byproduct materials with half-lives of less than 65 days, a list containing all the following:

(1) All areas currently and formerly designated as restricted areas.

(2) All areas outside of restricted areas that require documentation under subdivision 8 (c) 1 of this subsection.

(3) All areas outside of restricted areas where current and previous wastes have been buried as documented under 12VAC5-481-1060 .

(4) All areas outside of restricted areas that contain radioactive material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in 12VAC5-481-510 or apply for approval for disposal under 12VAC5-481-920 .

d. Records of the cost estimate performed for the decommissioning funding plan or the amount certified for decommissioning and records of the funding method used for assuring funds.

9. A licensee shall keep the records in subdivision 8 of this subsection until the site is decommissioned and approved by the agency for unrestricted use.

10. Prior to a licensed activity being transferred to another licensee under 12VAC5-481-500 B, the original licensee shall transfer all records under subdivision 8 of this subsection to the new licensee. The new licensee shall be responsible for maintaining the records until their license is terminated by the agency.

11. A person applying for a specific license authorizing the possession and use of more than 100 mCi of source material in a readily dispersible form shall submit a decommissioning funding plan as described in subdivision 6 of this subsection.

12. A person applying for a specific license authorizing the possession and use of quantities of source material greater than 10 mCi but less than or equal to 100 mCi in a readily dispersible form shall either:

a. Submit a decommissioning funding plan as described in subdivision 6 of this subsection; or

b. Submit a certification that financial assurance for decommissioning has been provided in the amount of $225,000 using one of the methods described in subdivision 7 of this subsection.

12VAC5-481-451. Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.

A. Any licensee who possesses or uses an aggregated quantity of Category 1 or Category 2 radioactive material equal to or in excess of those in subdivision 1 of this subsection shall establish a physical protection program that meets all requirements detailed in this section.

1. Radionuclides of concern.

Radionuclide	Category 1 (TBq)[1,2]	Category 1 (Ci)[1,2]	Category 2 (TBq)[1,2]	Category 2 (Ci)[1,2]
Am-241	60	1,620	0.6	16.2
Am-241/Be	60	1,620	0.6	16.2
Cf-252	20	540	0.2	5.4
Cm-244	50	1,350	0.5	13.5
Co-60	30	810	0.3	8.1
Cs-137	100	2,700	1	27
Gd-153	1,000	27,000	10	270
Ir-192	80	2,160	0.8	21.6
Pm-147	40,000	1,080,000	400	10,800
Pu-238	60	1,620	0.6	16.2
Pu-239/Be	60	1,620	0.6	16.2
Ra-226	40	1,080	0.4	10.8
Se-75	200	5,400	2	54
Sr-90 (Y-90)	1,000	27,000	10	270
Tm-170	20,000	540,000	200	5,400
Yb-169	300	8,100	3	81
Combinations of radioactive materials listed above[3]			See footnote 4 below	

[1]The aggregate activity of multiple, collocated sources of the same radionuclides should be included when the total activity equals or exceeds the Category 1 or Category 2 threshold.

[2]The primary values used for compliance are TBq. The curie (Ci) values are rounded to two significant figures for informational purposes only.

[3]Radioactive materials are to be considered aggregated or collocated if breaching a common physical barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material.

[4]If several radionuclides are aggregated, the sum of the ratios of the activity of each source, i of radionuclide, n, A (i,n), to the Category 1 or Category 2 threshold for radionuclide n, Q_n, listed for that radionuclide equals or exceeds one. [(aggregated source activity for radionuclide A) / (quantities of concern for radionuclide A)] + [(aggregated source activity for radionuclide B) / (quantities of concern for radionuclide B)] + etc. 1.

2. A licensee that possesses radioactive waste that contains Category 1 or Category 2 quantities of radioactive material is exempt from the requirements of this section.

3. A licensee that possesses radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg (4,409 lbs) is not exempt from the requirements of this section. The licensee shall implement the following requirements to secure the radioactive waste:

a. Use continuous physical barriers that allow access to the radioactive waste only through established access control points;

b. Use a locked door or gate with monitored alarm at the access control point;

c. Assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and

d. Immediately notify the local law-enforcement agency (LLEA) and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste.

B. Background investigations and access authorization program.

1. Personnel access authorization requirements for Category 1 or Category 2 quantities of radioactive material.

a. Each licensee that possesses an aggregated quantity of radioactive material that equals or exceeds the Category 2 threshold shall establish, implement, and maintain its access authorization program in accordance with the requirements in this subsection. An applicant for a new license and each licensee that would become newly subject to the requirements in this subsection upon an amendment request of its license shall implement the requirements of this subsection, as appropriate, before taking possession of an aggregated quantity of radioactive material that equals or exceeds the Category 2 threshold. Any licensee that has not previously implemented the increased control requirements of this section shall implement the provisions of this subsection before aggregating radioactive material to a quantity that equals or exceeds the

Category 2 threshold.

b. The licensee's access authorization program shall ensure that the individuals specified in subdivision 1 c of this subsection are trustworthy and reliable.

c. Licensees shall subject the following individuals to an access authorization program:

(1) Any individual whose assigned duties require unescorted access to Category 1 or Category 2 quantities of radioactive material; and

(2) Reviewing officials.

d. Licensees shall approve for unescorted access to Category 1 or Category 2 quantities of radioactive material only those individuals whose assigned job duties require unescorted access to Category 1 or Category 2 quantities of radioactive material.

e. Licensees need not subject the categories of individuals listed in subdivision 5 a of this subsection to the investigation elements of the access authorization program.

2. Access authorization program requirements.

a. Granting unescorted access authorization.

(1) Licensees shall implement the requirements of this subsection for granting initial or reinstated unescorted access authorization.

(2) Individuals who have been determined to be trustworthy and reliable shall also complete the security training required by subdivision C 2 c of this section before being allowed unescorted access to Category 1 or Category 2 quantities of radioactive material.

b. Reviewing officials.

(1) Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to Category 1 or Category 2 quantities of radioactive materials possessed by the licensee.

(2) Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation a certification that the reviewing official is deemed trustworthy and reliable by the licensee. The fingerprints of the named reviewing official shall be taken by a law-enforcement agency, a federal or state agency that provides fingerprinting services to the public, or a commercial fingerprinting service authorized by a state to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every 10 years in accordance with subdivision 3 c of this subsection.

(3) Reviewing officials shall be permitted to have unescorted access to Category 1 or Category 2 quantities of radioactive material.

(4) Reviewing officials cannot approve other individuals to act as reviewing officials.

(5) A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:

(a) The individual has undergone a background investigation that included fingerprinting and an FBI criminal history records check and has been determined to be trustworthy and reliable by the licensee; or

(b) The individual is subject to a category listed in subdivision 5 a of this subsection.

c. Informed consent.

(1) Licensees may not initiate a background investigation without the informed and signed consent of the subject individual. This consent shall include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. Before a final adverse determination, the licensee shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is developed during the background investigation. Licensees do not need to obtain signed consent from those individuals who meet the requirements of subdivision 3 b of this subsection. A signed consent shall be obtained prior to any reinvestigation.

(2) The subject individual may withdraw his consent at any time. Licensees shall inform the individual that:

(a) If an individual withdraws his consent, the licensee may not initiate elements of the background investigation that were not in progress at the time the individual withdrew his consent; and

(b) The withdrawal of consent for the background investigation is sufficient cause of denial or termination of unescorted access authorization.

d. Any individual who is applying for unescorted access authorization shall disclose the personal history information that is required by the licensee's access authorization program for the reviewing official to make a determination of the individual's trustworthiness and reliability. Refusal to provide, or the falsification of, any personal history information required by this subsection is sufficient cause for denial or termination of unescorted access.

e. Determination basis.

(1) The reviewing official shall determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access authorization based on an evaluation of all the information collected to meet the requirements of this subsection.

(2) The reviewing official may not permit any individual to have unescorted access until the reviewing official has evaluated all the information collected to meet the requirements of this subsection and determined that the individual is trustworthy and reliable. The reviewing official may deny unescorted access to any individual based on

information obtained at any time during the background investigation.

(3) The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.

(4) The reviewing official may terminate or administratively withdraw an individual's unescorted access authorization based on information obtained after the background investigation has been completed and the individual granted unescorted access information.

(5) Licensees shall maintain a list of persons currently approved for unescorted access authorization. When a licensee determines that a person no longer requires unescorted access or meets the access authorization requirement, the licensee shall remove the person from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to have unescorted access to the material.

f. Licensees shall develop, implement, and maintain written procedures for implementing the access authorization program. The procedures shall include the provisions for the notification of individuals who are denied unescorted access. The procedures shall include provisions for the review, at the request of the affected individual, of a denial or termination of unescorted access authorization. The procedures shall contain a provision to ensure that the individual is informed of the grounds for the denial or termination of unescorted access authorization and allow the individual an opportunity to provide additional relevant information.

g. Right to correct and complete information.

(1) Prior to any final adverse determination, licensees shall provide each individual subject to this subsection with the right to complete, correct, and explain information obtained as a result of the licensee's background investigation. Confirmation of receipt by the individual of this notification shall be maintained by the licensee for a period of one year from the date of the notification.

(2) If, after reviewing his criminal history record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, update, or explain anything in the record, the individual may initiate challenge procedures. These procedures include direct application by the individual challenging the record to the law-enforcement agency that contributed the questioned information or a direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division, ATTN: SCU, Mod. D-2, 1000 Custer Hollow Road, Clarksburg, WV 26306 as set forth in 28 CFR 16.30 through 28 CFR 16.34. In the latter case, the Federal Bureau of Investigation (FBI) will forward the challenge to the agency that submitted the data and will request that the agency verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division will make any change necessary in accordance with the information supplied by that agency. Licensees shall provide at

least 10 days for an individual to initiate action to challenge the results of an FBI criminal history records check after the record being made available for his review. The licensee may make a final adverse determination based upon the criminal history records only after receipt of the FBI's confirmation or correction of the record.

h. Records.

(1) The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material.

(2) The licensee shall retain a copy of the current access authorization program procedures as a record for three years after the procedure is no longer needed. If any portion of the procedure is superseded, the licensee shall retain the superseded material for three years after the record is superseded.

(3) The licensee shall retain the list of individuals approved for unescorted access authorization for three years after the list is superseded or replaced.

3. Background investigations.

a. Before allowing an individual unescorted access to Category 1 or Category 2 quantities of radioactive material or to the devices containing the material, licensees shall complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation shall encompass at least the seven years preceding the date of the background investigation or since the individual's 18th birthday, whichever is shorter. The background investigation shall include at a minimum:

(1) Fingerprinting and an FBI identification and criminal history records check in accordance with subdivision 4 of this subsection;

(2) Verification of true identity of the individual who is applying for unescorted access authorization. A licensee shall review official identification documents (e.g., driver's license; passport; government identification; certificate of birth issued by the state, province, or country of birth) and compare the documents to personal information data provided by the individual to identify any discrepancy in the information. Licensees shall document the type, expiration, and identification number of the identification document or maintain a photocopy of identifying documents on file in accordance with subdivision 6 of this subsection. Licensees shall certify in writing that the identification was properly reviewed and shall maintain the certification and all related documents for review upon inspection;

(3) Verification of employment history, including military history. Licensees shall verify the individual's employment with each previous employer for the most recent seven years before the date of application;

(4) Verification that the individual participated in the education process during the

claimed period;

(5) Completion of reference checks to determine the character and reputation of the individual who has applied for unescorted access authorization. Unless other references are not available, reference checks may not be conducted with any person who is known to be a close member of the individual's family, including but not limited to, the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks under this subsection shall be limited to whether the individual has been and continues to be trustworthy and reliable;

(6) To the extent possible, obtain independent information to corroborate the information provided by the individual (e.g., seek references not supplied by the individual); and

(7) If a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide the information or indicates an inability or unwillingness to provide information within a timeframe deemed appropriate by the licensee but at least after 10 business days of the request or if the licensee is unable to reach the entity, the licensee shall document the refusal, unwillingness, or inability in the record of investigation and attempt to obtain the information from an alternate source.

b. Individuals who have been determined to be trustworthy and reliable for unescorted access to Category 1 or Category 2 quantities of radioactive material in accordance with 12VAC5-481-451 , "Increased controls and fingerprinting," as effective on October 3, 2008, can continue to have unescorted access to Category 1 and Category 2 quantities of radioactive material without further investigation. These individuals shall be subject to the reinvestigation requirement of subdivision 3 c of this subsection.

c. Licensees shall conduct a reinvestigation every 10 years for any individual with unescorted access to Category 1 or Category 2 quantities of radioactive material. The reinvestigation shall consist of fingerprinting and an FBI identification and criminal history records check in accordance with subdivision 4 of this subsection. The reinvestigations shall be completed within 10 years of the date on which these elements were last completed.

4. Requirements for criminal history records checks of individuals granted unescorted access to Category 1 or Category 2 quantities of radioactive material.

a. General performance objective and requirements.

(1) Except for those individuals listed in subdivision 5 a of this subsection and those individuals grandfathered under subdivision 3 b of this subsection, each licensee subject to the provisions of this section shall fingerprint each individual who is to be permitted unescorted access to Category 1 or Category 2 quantities of radioactive material. The licensee shall submit all collected fingerprints to the NRC for transmission to the FBI. The licensee shall use the information received from the FBI as

part of the required background investigation to determine whether to grant or deny further unescorted access to Category 1 or Category 2 quantities of radioactive materials for that individual.

(2) The licensee shall notify each affected individual that his fingerprints will be used to secure a review of his criminal history record and shall inform him of the procedures for revising the record or adding explanations to the record.

(3) Fingerprinting is not required if a licensee is reinstating an individual's unescorted access authorization to Category 1 or Category 2 quantities of radioactive material if:

(a) The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of his unescorted access authorization; and

(b) The previous access was terminated under favorable conditions.

(4) Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to Category 1 or Category 2 quantities of radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee based upon a background investigation conducted under this subsection, regulations or Fingerprint Orders from another agreement state, or 10 CFR Part 73. An existing criminal history records check file may be transferred to the licensee asked to grant unescorted access in accordance with the provisions of subdivision 6 c of this subsection.

(5) Licensees shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to Category 1 or Category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

b. Prohibitions.

(1) Licensees may not base a final determination to deny an individual unescorted access authorization to Category 1 or Category 2 quantities of radioactive material solely on the basis of information received from the FBI involving:

(a) An arrest more than one year old for which there is no information of the disposition of the case; or

(b) An arrest that resulted in dismissal of the charge or an acquittal.

(2) Licensees may not use information received from a criminal history records check obtained under this subsection in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

c. Procedures for processing of fingerprint checks.

(1) For the purpose of complying with this subsection, licensees shall submit to the U.S. Nuclear Regulatory Commission, Director, Division of Facilities and Security, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop T-03B46M, Rockville, MD, 20852-2738, one completed, legible standard fingerprint card (form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan, or, where practicable, other fingerprint record for each individual requiring unescorted access to Category 1 or Category 2 quantities of radioactive material. Copies of these forms may be obtained by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling (630) 829-9565, or by email to forms.resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at http://www.nrc.gov/site-help/e-submittals.html.

(2) Fees for processing of fingerprint cards are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to the "U.S. NRC." (For guidance on making electronic payments, contact the Security Branch, Division of Facilities and Security at (301) 492-3531.) Combined payment for multiple applications is acceptable. The NRC publishes the amount of the fingerprint check application fee on the NRC public website. To find the current fee amount, go to the Electronic Submittals page at http://www.nrc.gov/site-help/e-submittals.html and see the link for the Criminal History Program under Electronic Submission Systems.

(3) The NRC will forward to the submitting licensee all data received from the FBI as a result of the licensee's application for a criminal history records check.

5. Relief.

a. Fingerprinting, identification and criminal history records checks, and other elements of the background investigation required by this subsection are not required for the following individuals prior to granting unescorted access to Category 1 or Category 2 quantities of radioactive material:

(1) An employee of the NRC or of the executive branch of the U.S. government who has undergone fingerprinting for a prior U.S. government criminal history records check;

(2) A member of Congress;

(3) An employee of a member of Congress or congressional committee who has undergone fingerprinting for a prior U.S. government criminal history records check;

(4) The governor of a state or his designated state employee representative;

(5) Federal, state, or local law-enforcement personnel;

(6) State radiation control program directors and state homeland security advisors or their designated employee representatives;

(7) State radiation program employees conducting security inspections on behalf of the

NRC under an agreement executed under § 274i of the Atomic Energy Act (42 USC § 2021i);

(8) Representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S./IAEA Safeguards Agreement who have been certified by the NRC;

(9) Emergency response personnel who are responding to an emergency;

(10) Commercial vehicle drivers for road shipments of Category 2 quantities of radioactive material;

(11) Package handlers at transportation facilities such as freight terminals and railroad yards;

(12) Any individual who has an active federal security clearance and provides the appropriate documentation. Written confirmation from the agency or employer that granted the federal security clearance or reviewed the criminal history records check shall be provided to the licensee. The licensee shall retain this documentation for a period of three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material; and

(13) Any individual employed by a service provider licensee for whom the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to Category 1 or Category 2 quantities of radioactive material. Written verification from the service provider shall be provided to the licensee. The licensee shall retain the documentation for a period of three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material.

b. Fingerprinting and identification and criminal history records checks required by this subsection are not required for an individual who has had a favorably adjudicated U.S. Government criminal history records check within the last five years, under a comparable U.S. Government program involving fingerprinting and an FBI identification and criminal history records check, and the individual provides the appropriate documentation. Written confirmation from the agency or employer that reviewed the criminal history records check shall be provided to the licensee. The licensee shall retain this documentation for a period of three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material. These programs include, but are not limited to:

(1) National Agency Check;

(2) Transportation Worker Identification Credentials (TWIC) under 49 CFR Part 1572;

(3) Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances under 27 CFR Part 555;

(4) Health and Human Services security risk assessments for possession and use of

select agents and toxins under 42 CFR Part 73;

(5) Hazardous material security threat assessment for hazardous material endorsement to commercial driver's license under 49 CFR Part 1572; and

(6) Customs and Border Protection's Free and Secure Trade (FAST) Program.

6. Protection of information.

a. Each licensee that obtains background information on an individual under this subsection shall establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure.

b. The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his representative, or to those who have a need to have access to the information in performing assigned duties in the process of granting or denying unescorted access to Category 1 or Category 2 quantities of radioactive material. No individual authorized to have access to the information may disseminate the information to any other individual who does not have a need to know.

c. The personal information obtained on an individual from a background investigation may be provided to another licensee:

(1) Upon the individual's written request to the licensee holding the data to disseminate the information contained in that individual's file; and

(2) The recipient licensee verifies information such as name, date of birth, social security number, gender, and other applicable physical characteristics.

d. The licensee shall make background investigation records obtained under this subsection available for examination by an authorized representative of the agency to determine compliance with the regulations and laws.

e. The licensee shall retain all fingerprint and criminal history records (including data indicating no record) received from the FBI, or a copy of these records if the individual's file has been transferred, on an individual for three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material.

7. Access authorization program review.

a. Each licensee shall be responsible for the continuing effectiveness of the access authorization program. Each licensee shall ensure that access authorization programs are reviewed to confirm compliance with the requirements of this subsection and that comprehensive actions are taken to correct any noncompliance that is identified. The review program shall evaluate all program performance objectives and requirements. The review shall be performed at least annually.

b. The results of the reviews, along with all recommendations, shall be documented. Each review report shall identify conditions that are adverse to the proper performance

of the access authorization program; the cause of the conditions and, when appropriate, recommend corrective actions; and corrective actions taken. The licensee shall review the findings and take additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

c. Review records shall be maintained for three years.

C. Physical protection requirements during use.

1. Security program.

a. Each licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements of this subsection. An applicant for a new license and each licensee that would become newly subject to the requirements of this subsection upon an amendment request for modification of its license shall implement the requirements of this subsection, as appropriate, before taking possession of an aggregated Category 1 or Category 2 quantity of radioactive material. Any licensee that has not previously implemented the requirements of this subsection shall provide written notification to the agency at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold.

b. Each licensee shall establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to Category 1 or Category 2 quantities of radioactive material.

c. Each licensee's security program shall include the program features, as appropriate, described in subdivisions 2 through 8 of this subsection.

2. General security program requirements.

a. Security plan.

(1) Each licensee identified in subdivision 1 a of this subsection shall develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by this subsection. The security plan shall, at a minimum, (i) describe the measures and strategies used to implement the requirements of this subsection and (ii) identify the security resources, equipment, and technology used to satisfy the requirements of this subsection.

(2) The security plan shall be reviewed and approved by the individual with overall responsibility for the security program.

(3) A licensee shall revise its security plan as necessary to ensure the effective implementation of agency requirements. The licensee shall ensure that (i) the revision has been reviewed and approved by the individual with overall responsibility for the security program and (ii) the affected individuals are instructed on the revised plan

before the changes are implemented.

(4) The licensee shall retain a copy of the current security plan as a record for three years after the security plan is no longer required. If any portion of the plan is superseded, the licensee shall retain the superseded material for three years after the record is superseded.

b. Implementing procedures.

(1) The licensee shall develop and maintain written procedures that document how the requirements of this subsection and the security plan will be met.

(2) The implementing procedures and revisions to these procedures shall be approved in writing by the individual with overall responsibility for the security program.

(3) The licensee shall retain a copy of the current procedure as a record for three years after the procedure is no longer needed. Superseded portions of the procedure shall be retained for three years after the record is superseded.

c. Training.

(1) Each licensee shall conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training shall include at a minimum, instruction on:

(a) The licensee's security program and procedures to secure Category 1 or Category 2 quantities of radioactive material, and the purpose and function of the security measures employed;

(b) The responsibility to report promptly to the licensee any condition that causes or may cause a violation of agency requirements;

(c) The responsibility of the licensee to report promptly to the local law-enforcement agency and the agency any actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material; and

(d) The appropriate response to security alarms.

(2) In determining those individuals who shall be trained on the security program, the licensee shall consider each individual's assigned activities during authorized use and response to potential situations involving actual or attempted theft, diversion, or sabotage of Category 1 or Category 2 quantities of radioactive material. The extent of the training shall be commensurate with the individual's potential involvement in the security of Category 1 or Category 2 quantities of radioactive material.

(3) Refresher training shall be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program. This training shall include (i) review of the training requirements of this subsection and changes made to the security program since the last training; (ii) reports on all relevant security issues,

problems, and lessons learned; (iii) relevant results of agency inspections; and (iv) relevant results of the licensee's program review and testing and maintenance.

(4) The licensee shall maintain records of the initial and refresher training for three years from the date of the training. The training records shall include dates of the training, topics covered, a list of licensee personnel in attendance, and related information.

d. Protection of information.

(1) Licensees authorized to possess Category 1 or Category 2 quantities of radioactive material shall limit access to and prevent the unauthorized disclosure of their security plan, implementing procedures, and the list of individuals who have been approved for unescorted access.

(2) Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to and for proper handling and protection against unauthorized disclosure of the security plan and implementing procedures.

(3) Before granting an individual access to the security plan or implementing procedures, licensees shall:

(a) Evaluate an individual's need to know the security plan or implementing procedures; and

(b) If the individual has not been authorized for unescorted access to Category 1 or Category 2 quantities of radioactive material, the licensee shall complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in subdivisions B 3 a (2) through (7) of this section.

(4) Licensees need not subject any individual to background investigation elements for protection of information if that individual is included in the categories of individuals listed in subdivisions B 5 a (1) through (12) of this section or is a security service provider employee, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in subdivisions B 3 a (2) though (7) of this subsection, has been provided by the security service provider.

(5) The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan or implementing procedures.

(6) Licensees shall maintain a list of persons currently approved for access to the security plan or implementing procedures. When a licensee determines that a person no longer needs access to the security plan or implementing procedures or no longer meets the access authorization requirements for access to the information, the licensee shall

remove the person from the approved list as soon as possible, but no later than seven working days after the determination, and take prompt measures to ensure that the individual is unable to obtain the security plan or implementing procedures.

(7) When not in use, the licensee shall store its security plan and implementing procedures in a manner to prevent unauthorized access. Information stored in nonremovable electronic form shall be password protected.

(8) The licensee shall retain as a record a copy of the information protection procedures and the list of individuals approved for access to the security plan or implementing procedures for three years after the document has been superseded.

3. Local law-enforcement agency (LLEA) coordination.

a. A licensee subject to this subsection shall coordinate, to the extent practicable, with an LLEA for responding to threats to the licensee's facility, including any necessary armed response. The information provided to the LLEA shall include:

(1) A description of the facilities and the Category 1 and Category 2 quantities of radioactive materials along with a description of the licensee's security measures that have been implemented to comply with this subsection; and

(2) A notification that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of material.

b. The licensee shall notify the agency within three business days if:

(1) The LLEA has not responded to the request for coordination within 60 days of the coordination request; or

(2) The LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities.

c. The license shall document its efforts to coordinate with the LLEA. The documentation shall be kept for three years.

d. The licensee shall coordinate with the LLEA at least every 12 months, or when changes to the facility design or operation adversely affect the potential vulnerability of the licensee's material to theft, sabotage, or diversion.

4. Security zones.

a. Licensees shall ensure that all aggregated Category 1 or Category 2 quantities of radioactive material are used or stored within licensee-established security zones. Security zones may be permanent or temporary.

b. Temporary security zones shall be established as necessary to meet the licensee's transitory or intermittent business activities, such as periods of maintenance, source delivery, and source replacement.

c. Security zones shall, at a minimum, allow unescorted access only to approved individuals by:

(1) Isolation of Category 1 and Category 2 quantities of radioactive materials by the use of continuous physical barriers that allow access to the security zone only through established access control points. A physical barrier is a natural or man-made structure or formation sufficient for the isolation of the Category 1 or Category 2 quantities of radioactive material within a security zone;

(2) Direct control of the security zone by approved individuals at all times; or

(3) A combination of continuous physical barriers and direct control.

d. For Category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee shall, at a minimum, provide sufficient individuals approved for unescorted access to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow such activities.

e. Individuals not approved for unescorted access to Category 1 or Category 2 quantities of radioactive material shall be escorted by an approved individual when in a security zone.

5. Monitoring, detection, and assessment.

a. Monitoring and detection.

(1) Licensees shall establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones. Licensees shall provide the means to maintain continuous monitoring and detection capability in the event of a loss of the primary power source, or provide for an alarm and response in the event of a loss of this capability to continuously monitor and detect unauthorized entries.

(2) Monitoring and detection shall be performed by:

(a) A monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility;

(b) Electronic devices for intrusion detection alarms that will alert nearby facility personnel;

(c) A monitored video surveillance system;

(d) Direct visual surveillance by approved individuals located within the security zone; or

(e) Direct visual surveillance by a licensee designed individual located outside the security zone.

(3) A licensee subject to this subsection shall also have a means to detect unauthorized removal of the radioactive material from the security zone. This detection capability shall provide:

(a) For Category 1 quantities of radioactive material, immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. Such immediate detection capability shall be provided by electronic sensors linked to an alarm, continuous monitored video surveillance, or direct visual surveillance; and

(b) For Category 2 quantities of radioactive material, weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.

b. Licensees shall immediately assess each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion.

c. For personnel and automated or electronic systems supporting the licensee's monitoring, detection, and assessments system, licensees shall:

(1) Maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems; and

(2) Provide an alternate communication capability for personnel, and an alternative data transmission and processing capability, in the event of a loss of the primary means of communication or data transmission and processing. Alternative communications and data transmissions systems may not be subject to the same failure modes as the primary systems.

d. Licensees shall immediately respond to any actual or attempted unauthorized access to the security zones, or actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material at licensee facilities or temporary job sites. For any unauthorized access involving an actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material, the licensee's response shall include requesting, without delay, an armed response from the LLEA.

6. Maintenance and testing.

a. Each licensee subject to this subsection shall implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition and are capable of performing their intended function when needed. The equipment relied on to meet the security requirements of this subsection shall be inspected and tested for operability and performance at the manufacturer's suggested frequency. If there is no frequency suggested by the manufacturer or the frequency specified is greater than three months, the testing shall be performed at least quarterly, not to exceed three months.

b. The licensee shall maintain records on the maintenance and testing activities for

three years.

7. Requirements for mobile devices. Each licensee that possesses mobile devices containing Category 1 or Category 2 quantities of radioactive material shall:

a. Have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee; and

b. For devices in or on a vehicle or trailer, unless the health and safety requirements for a site prohibit the disabling of the vehicle, the licensee shall utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee. Licensees shall not rely on the removal of an ignition key to meet this requirement.

8. Security program review.

a. Each licensee shall be responsible for the continuing effectiveness of the security program. Each licensee shall ensure that the security program is reviewed to confirm compliance with the requirements of this subsection and that comprehensive actions are taken to correct any noncompliance that is identified. The review shall include the radioactive material security program content and implementation. The review shall be conducted at least annually, not to exceed 12 months.

b. The results of the review, along with all recommendations, shall be documented. Each review report shall identify conditions that are adverse to the proper performance of the security program, the cause of the condition, corrective actions taken, and, when appropriate, recommend corrective actions. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

c. The licensee shall maintain the review documentation for three years.

9. Reporting of events.

a. The licensee shall immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantity of radioactive material. As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee shall notify the agency by telephone at 804-864-8150 during normal business hours and 804-624-2400 after hours. In no case shall the notification to the agency be later than four hours after the discovery of any attempted or actual theft, sabotage, or diversion.

b. The licensee shall assess any suspicious activity related to possible theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material and notify the LLEA as appropriate. As soon as possible but not later than four hours after notifying the LLEA, the licensee shall notify the agency by telephone 804-864-8150 during normal business hours and 804-624-2400 after hours.

c. The initial telephonic notification shall be followed within a period of 30 days by a written report submitted to the agency. The report shall include sufficient information for agency analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

D. Physical protection in transit.

1. Additional requirements for transfer of Category 1 and Category 2 quantities of radioactive material. A licensee transferring a Category 1 or Category 2 quantity of radioactive material to a licensee of the agency, the NRC, or another agreement state shall meet the license verification provisions listed in this subdivision instead of those listed in 12VAC5-481-570 .

a. Any licensee transferring Category 1 quantities of radioactive material to a licensee of the agency, the NRC, or another agreement state, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred and that the licensee is authorized to receive radioactive material at the location requested for delivery. If the verification is conducted by contacting the license-issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

b. Any licensee transferring Category 2 quantities of radioactive material to a licensee of the agency, the NRC, or another agreement state, prior to conducting such transfer, shall verify with the NRC's license verification system or the license-issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. If the verification is conducted by contacting the license-issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

c. In an emergency where the licensee cannot reach the license-issuing authority and the license verification system is nonfunctional, the licensee may accept a written certification by the transferee that it is authorized by license to receive the type, form, and quantity of radioactive material to be transferred. The certification shall include the license number, current revision number, issuing agency, expiration date, and for a Category 1 shipment, the authorized address. The licensee shall keep a copy of the certification. The certification shall be confirmed by use of the NRC's license verification system or by contacting the license-issuing authority by the end of the next business day.

d. The transferor shall keep a copy of the verification documentation as a record for three years.

2. Applicability of physical protection of Category 1 and Category 2 quantities of radioactive material during transit.

a. For shipments of category 1 quantities of radioactive material, each shipping licensee

shall comply with the requirements for physical protection contained in subdivisions 3 a, 3 e, 4, 5 a (1), 5 b (1), 5 c, 6 a, 6 c, 6 e, 6 g, and 6 h of this subsection.

b. For shipments of Category 2 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in subdivisions 3 b through 3 e, 5 a (2), 5 a (3), 5 b (2), 5 c, 6 b, 6 d, 6 f, 6 g, and 6 h of this subsection.

c. The shipping licensee shall be responsible for meeting the requirements of this subsection unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under this subsection.

3. Preplanning and coordination of shipment of Category 1 or Category 2 quantities of radioactive material.

a. Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a Category 1 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall:

(1) Preplan and coordinate shipment arrival and departure times with the receiving licensee;

(2) Preplan and coordinate shipment information with the governor or the governor's designee of any state through which the shipment will pass to discuss the state's intention to provide law-enforcement escorts and identify safe havens; and

(3) Document the preplanning and coordination activities.

b. Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a Category 2 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee shall document the coordination activities.

c. Each licensee that receives a shipment of a Category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

d. Each licensee that transports or plans to transport a shipment of a Category 2 quantity of radioactive material and determines that the shipment will arrive after the no-later-than arrival time provided pursuant to subdivision 3 b of this subsection, shall promptly notify the receiving licensee of the new no-later-than arrival time.

e. The licensee shall retain a copy of the documentation for preplanning and coordination and any revision thereof as a record for three years.

4. As specified in subdivision 3 of this subsection, each licensee shall provide advance notification to the agency and the governor of a state, or the governor's designee, of the shipment of licensed material in a Category 1 quantity, through or across the boundary of

the state, before the transport or delivery to a carrier for transport of the licensed material outside the confines of the licensee's facility or other place of use or storage.

a. Procedures for submitting advance notification;

(1) The notification shall be made to the agency and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of governors and governor's designees is available on the NRC website at http://nrc-stp.ornl.gov/special/designee.pdf. The notification to the agency shall be in accordance with 12VAC5-481-150 .

(2) A notification delivered by mail shall be postmarked at least seven days before transport of the shipment commences at the shipping facility.

(3) A notification delivered by any means other than mail shall reach the agency at least four days before the transport of the shipment commences and shall reach the office of the governor or the governor's designee at least four days before transport of a shipment within or through the state.

b. Each advance notification of shipment of Category 1 quantities of radioactive material shall contain the following information, if available at the time of the notification:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the Category 1 radioactive material;

(2) The license numbers of the shipper and receiver;

(3) A description of the radioactive material contained in the shipment, including the radionuclides and quantity;

(4) The point of origin of the shipment and the estimated time and date that shipment will commence;

(5) The estimated time and date that the shipment is expected to enter each state along the route;

(6) The estimated time and date of arrival for the shipment at the destination; and

(7) A point of contact, with a telephone number, for current shipment information.

c. Revision notice.

(1) The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the agency and the governor of the state or the governor's designee.

(2) A licensee shall promptly notify the agency and governor of the state or the governor's designee of any changes to the information provided in accordance with this subdivision.

d. Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the agency and the governor of each state or to the governor's designee previously notified. The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled.

e. The licensee shall retain a copy of the advance notification and any revision and cancellation notices as a record for three years.

5. Requirements for physical protection of Category 1 and Category 2 quantities of radioactive material during shipment.

a. Shipments by road.

(1) Each licensee who transports or delivers to a carrier for transport in a single shipment a Category 1 quantity of radioactive material shall:

(a) Ensure that movement control centers are established that maintain position information from a remote location. These control centers shall monitor shipments 24 hours a day, seven days a week and have the ability to communicate immediately, in an emergency, with the appropriate law-enforcement agencies;

(b) Ensure that redundant communications are established that allow the transport to contact the escort vehicle, when an escort vehicle is used, and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication;

(c) Ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center shall provide positive confirmation of the location, status, and control over the shipment. The movement control center shall be prepared to promptly implement preplanned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route;

(d) Provide an individual to accompany the driver for those highway shipments with a driving time period greater than the maximum number of allowable hours of service in a 24-hour duty day as established by the U.S. Department of Transportation Federal Motor Carrier Safety Administration. The accompanying individual may be another driver; and

(e) Develop written normal and contingency procedures to address (i) notifications to the communication center and law-enforcement agencies; (ii) communication protocols that shall include a strategy for the use of authentication codes and duress codes and provisions for refueling and other stops, detours, and locations where communication is

expected to be temporarily lost; (iii) loss of communication; and (iv) responses to an actual or attempted theft or diversion of a shipment.

(f) Each licensee who makes arrangements for the shipment of Category 1 quantities of radioactive material shall ensure that drivers, accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.

(2) Each licensee that transports Category 2 quantities of radioactive material shall maintain constant control and surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.

(3) Each licensee who delivers to a carrier for transport in a single shipment a Category 2 quantity of radioactive material shall:

(a) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and surveillance, the package tracking system shall allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control;

(b) Use carriers that maintain constant control and surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(c) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

b. Shipments by rail.

(1) Each licensee who transports, or delivers to a carrier for transport, in a single shipment a Category 1 quantity of radioactive material shall:

(a) Ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications center. The communications center shall provide positive confirmation of the location of the shipment and its status. The communications center shall implement preplanned procedures in response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route; and

(b) Ensure that periodic reports to the communications center are made at preset intervals.

(2) Each licensee who transports, or delivers to a carrier for transport, in a single shipment a Category 2 quantity of radioactive material shall:

(a) Use carriers that have established package tracking systems. An established package

tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and surveillance, the package tracking system shall allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control;

(b) Use carriers that maintain constant control and surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(c) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

c. Each licensee who makes arrangements for the shipment of Category 1 quantities of radioactive material shall immediately conduct an investigation upon discovery that a Category 1 shipment is lost or missing. Each licensee who makes arrangements for the shipment of Category 2 quantities of radioactive material shall immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

6. Reporting of events.

a. The shipping licensee shall notify the appropriate LLEA and the agency within one hour of its determination that a shipment of Category 1 quantities of radioactive material is lost or missing. The appropriate LLEA would be the law-enforcement agency in the area of the shipment's last confirmed location. During the investigation required by this subsection, the shipping licensee will provide agreed upon updates to the agency on the status of the investigation.

b. The shipping licensee shall notify the agency within four hours of its determination that a shipment of Category 2 quantities of radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located and secure, the licensee shall immediately notify the agency.

c. The shipping licensee shall notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft of diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a Category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee shall notify the agency upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of Category 1 radioactive material.

d. The shipping licensee shall notify the agency as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of a Category 2 quantity of radioactive material.

e. The shipping licensee shall notify the agency and the LLEA as soon as possible upon

recovery of any lost or missing Category 1 quantities of radioactive material.

f. The shipping licensee shall notify the agency as soon as possible upon recovery of any lost or missing Category 2 quantities of radioactive material.

g. The initial telephonic notification required by subdivisions 6 a through 6 d of this subsection shall be followed within a period of 30 days by a written report submitted to the agency. The report shall include the following information:

(1) A description of the licensed material involved, including kind, quantity, and chemical and physical form;

(2) A description of the circumstances under which the loss or theft occurred;

(3) A statement of disposition, or probable disposition, of the licensed material involved;

(4) Actions that have been taken, or will be taken, to recover the material; and

(5) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

h. Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

E. Records.

1. Each record required by this section shall be legible throughout the retention period specified. The record may be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications shall include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

2. Licensees shall maintain the records that are required by this section for the period specified. If a retention period is not otherwise specified, these records shall be retained until the agency terminates the facility's license. All records related to this section may be destroyed upon agency termination of the facility license.

12VAC5-481-460. (Repealed.)

12VAC5-481-470. Special Requirements for Specific Licenses of Broad Scope.

This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing holders of such licenses. (Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment,

device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the Nuclear Regulatory Commission, Washington, D.C. 20555-0001.)

A. The different types of broad scope licenses are set forth below:

1. A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

2. A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in 12VAC5-481-3760 , for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in 12VAC5-481-3760 , Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 12VAC5-481-3760 , Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

3. A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in 12VAC5-481-3760 , for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in 12VAC5-481-3760 , Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 12VAC5-481-3760 , Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

B. An application for a Type A specific license of broad scope will be approved if:

1. The applicant satisfies the general requirements specified in 12VAC5-481-450;

2. The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

3. The applicant has established administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control and accounting, and management review that are necessary to assure safe operations, including:

a. The establishment of a radiation safety committee composed of such persons as a

radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

b. The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

c. The establishment of appropriate administrative procedures to assure:

(1) Control of procurement and use of radioactive material;

(2) Completion of safety evaluations of proposed uses of radioactive material that take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(3) Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with subdivision 3 c (2) of this subsection prior to use of the radioactive material.

C. An application for a Type B specific license of broad scope will be approved if:

1. The applicant satisfies the general requirements specified in 12VAC5-481-450; and

2. The applicant has established administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control and accounting, and management review that are necessary to assure safe operations, including:

a. The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters, and

b. The establishment of appropriate administrative procedures to assure,

(1) Control of procurement and use of radioactive material,

(2) Completion of safety evaluations of proposed uses of radioactive material that take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures, and

(3) Review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with subdivision 2 b (2) of this subsection prior to use of the radioactive material.

D. An application for a Type C specific license of broad scope will be approved if:

1. The applicant satisfies the general requirements specified in 12VAC5-481-450;

2. The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

a. A college degree at the bachelor level, or equivalent training and experience, in the

physical or biological sciences or in engineering, and

b. At least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

3. The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, recordkeeping, material control and accounting, and management review necessary to assure safe operations.

E. Specific licenses of broad scope are subject to the following conditions:

1. Unless specifically authorized, persons licensed pursuant to 12VAC5-481-470 shall not:

a. Conduct tracer studies in the environment involving direct release of radioactive material;

b. Receive, acquire, own, possess, use, or transfer devices containing 3.7 PBq (100,000 Ci) or more of radioactive material in sealed sources used for irradiation of materials;

c. Conduct activities for which a specific license issued by the agency under Part III (12VAC5-481-380 et seq.), Part V (12VAC5-481-1170 et seq.) or Part VII (12VAC5-481-1660 et seq.) of this chapter is required; or

d. Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

2. Each Type A specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

3. Each Type B specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

4. Each Type C specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of subsection D of this section.

12VAC5-481-480. Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices That Contain Radioactive Material.

A. Reserved.

B. Licensing the distribution of radioactive material in exempt quantities. (Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing radioactive material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the Nuclear Regulatory Commission, Washington, DC 20555-0001.)

C. Licensing the manufacture or initial transfer of devices to persons generally licensed under 12VAC5-481-430 B.

1. An application for a specific license to manufacture or initially transfer devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 12VAC5-481-430 B or equivalent regulations of the NRC, or another agreement state will be approved if:

a. The applicant satisfies the general requirements of 12VAC5-481-450;

b. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(1) The device can be safely operated by persons not having training in radiological protection;

(2) Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar quarter a dose in excess of 10% of the limits specified in 12VAC5-481-640; and

(3) Under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in 12VAC5-481-3580 , Column IV;

c. Each device bears a durable, legible, clearly visible label or labels approved by the agency, which contain in a clearly identified and separate statement:

(1) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device; documents such as operating and service manuals may be identified in the label and used to provide this information;

(2) The requirement, or lack of requirement, for leak testing, or for testing any "on-off" mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(3) The information called for in one of the following statements, as appropriate, in the

same or substantially similar form:

(a) The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the Nuclear Regulatory Commission or a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION—RADIOACTIVE MATERIAL

_____Name of manufacturer or initial transferor

(b) The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent, and the regulations of a licensing state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited. (The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.)

CAUTION—RADIOACTIVE MATERIAL

_____Name of manufacturer or initial transferor;

d. Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, and the words, "Caution Radioactive Material," the radiation symbol described in 12VAC5-481-850 , and the name of the manufacturer or initial distributor;

e. Each device meeting the criteria of 12VAC5-481-430 B 4 m bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separate, or the device if the source housing is not separable, that includes the words, "Caution Radioactive Material," and, if practicable, the radiation symbol described in 12VAC5-481-850; and

f. The device has been registered in the Sealed Source and Device Registry.

2. In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the agency will consider information that includes, but is not limited to:

a. Primary containment or source capsule;

b. Protection of primary containment;

c. Method of sealing containment;

d. Containment construction materials;

e. Form of contained radioactive material;

f. Maximum temperature withstood during prototype tests;

g. Maximum pressure withstood during prototype tests;

h. Maximum quantity of contained radioactive material;

i. Radiotoxicity of contained radioactive material; and

j. Operating experience with identical devices or similarly designed and constructed devices.

3. In the event the applicant desires that the general licensee under 12VAC5-481-430 B, or under equivalent regulations of the NRC, or another agreement state, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and basis for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10% of the limits specified in 12VAC5-481-640 .

4. Each person licensed under this subsection to distribute devices to generally licensed persons shall:

a. Furnish a copy of the general license contained in 12VAC5-481-430 B to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in 12VAC5-481-430 B;

b. Furnish a copy of the general license contained in the NRC's, or another agreement state's, regulation equivalent to 12VAC5-481-430 B, or alternatively, furnish a copy of the general license contained in 12VAC5-481-430 B to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the NRC, or another agreement state. If a copy of the general license in 12VAC5-481-430 B is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the NRC, or another agreement state, under requirements substantially the same as those in 12VAC5-481-430 B;

c. Report to the agency all transfers of such devices to persons for use under the general license in 12VAC5-481-430 B. Such report shall identify each general licensee by name

and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under 12VAC5-481-430 B during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter;

d. Furnish reports to other agencies.

(1) Report to the NRC all transfers of such devices to persons for use under the NRC's general license in 10 CFR 31.5.

(2) Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to this subsection for use under a general license in that state's regulations equivalent to 12VAC5-481-430 B.

(3) Such reports shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person.

(4) If no transfers have been made to NRC general licensees during the reporting period, this information shall be reported to the NRC.

(5) If no transfers have been made to general licensees within a particular state during the reporting period, this information shall be reported to the responsible state agency upon request of that agency; and

e. Keep records showing the name, address, and the point of contact for each general licensee to whom he directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in 12VAC5-481-430 B, or equivalent regulations of the NRC or another agreement state. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of subdivision 4 of this subsection.

f. If a notification of bankruptcy has been made under 12VAC5-481-500 E or the license is to be terminated, each person licensed under this section shall provide, upon request, to the agency, the NRC and to any appropriate agreement state, records of final disposition required under subdivision 4 e of this subsection.

g. The licensee shall maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by this section shall be maintained for a period of three years following the date of the recorded event.

D. Special requirements for the manufacture, initial transfer, assembly, or repair of luminous safety devices for use in aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under 12VAC5-481-430 D will be approved if:

1. The applicant satisfies the general requirements specified in 12VAC5-481-450 .

2. The applicant submits sufficient information regarding each device pertinent to evaluation of the potential radiation exposure, including:

a. Chemical and physical form and maximum quantity of tritium or promethium-147 in each device;

b. Details of construction and design;

c. Details of the method of binding or containing the tritium or promethium-147;

d. Procedures for and results of prototype testing to demonstrate that the tritium or promethium-147 will not be released to the environment under the most severe conditions likely to be encountered in normal use;

e. Quality assurance procedures to be followed that are sufficient to ensure compliance with subdivision 8 of this subsection; and

f. Any additional information, including experimental studies and tests, required by the NRC to facilitate a determination of the safety of the device.

3. Each device will contain no more than 10 curies of tritium or 300 millicuries of promethium-147. The levels of radiation from each device containing promethium-147 will not exceed 0.5 millirad per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber.

4. The agency determines that:

a. The method of incorporation and binding of the tritium or promethium-147 in the device is such that the tritium or promethium-147 will not be released under the most severe conditions likely to be encountered in normal use and handling of the device;

b. The tritium or promethium-147 is incorporated or enclosed so as to preclude direct physical contact with it by any person;

c. The device is so designed that it cannot easily be disassembled; and

d. Prototypes of the device have been subjected to and have satisfactorily passed the tests required by subdivision 5 of this subsection.

5. The applicant shall subject at least five prototypes of the device to tests as follows:

a. The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

b. The devices are inspected for evidence of physical damage and for loss of tritium or promethium-147 after each stage of testing using methods of inspection adequate for determining compliance with the criteria in subdivision 5 c of this subsection.

c. Device designs are rejected for which the following has been detected for any unit:

(1) A leak resulting in a loss of 0.1% or more of the original amount of tritium or promethium-147 from the device;

(2) Surface contamination of tritium or promethium-147 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

(3) Any other evidence of physical damage.

6. The device has been registered in the Sealed Source and Device Registry.

7. Labeling.

a. A person licensed to manufacture, assemble, or initially transfer devices containing tritium or promethium-147 for distribution to persons generally licensed under 12VAC5-481-430 D, except as provided in subdivision 7 b of this subsection, shall affix to each device a label containing the radiation symbol prescribed by 12VAC5-481-850 , such other information as may be required by the agency including disposal instructions when appropriate, and the following or a substantially similar statement that contains the information in the following statement:

The receipt, possession, use, and transfer of this device, Model* _____, Serial No.*_____, containing _____ (Identity and quantity of radioactive material) are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION--RADIOACTIVE MATERIAL

_____

(Name of manufacturer, assembler, or initial transferor.)*

*The model, serial number, and name of manufacturer, assembler, or initial transferor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.

b. If the agency determines that it is not feasible to affix a label to the device containing all the information called for in subdivision 7 a of this subsection, it may waive those

requirements and require the following:

(1) A label is affixed to the device identifying:

(i) The manufacturer, assembler, or initial transferor; and

(ii) The type of radioactive material; and

(2) A leaflet bearing the following information be enclosed in or accompany the container in which the device is shipped:

(i) The name of the manufacturer, assembler, or initial transferor;

(ii) The type and quantity of radioactive material;

(iii) The model number;

(iv) A statement that the receipt, possession, use, and transfer of the device are subject to a general license or the equivalent and the regulations of the NRC or of an agreement state; and

(v) Such other information as may be required by the agency, including disposal instructions when appropriate.

8. Quality assurance; prohibition of transfer.

a. Each person licensed under this subsection shall visually inspect each device and shall reject any that has an observable physical defect that could adversely affect containment of the tritium or promethium-147.

b. Each person licensed under this subsection shall:

(1) Maintain quality assurance systems in the manufacture of the luminous safety device in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

(2) Subject inspection lots to acceptance sampling procedures, by procedures specified in subdivision 8 c of this subsection and in the license issued under this subsection, to provide at least 95% confidence that the lot tolerance percent defective of 5.0% will not be exceeded.

c. The licensee shall subject each inspection lot to the following:

(1) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as absolute pressure and water immersion.

(2) Inspection for evidence of physical damage, containment failure, or for loss of tritium or promethium-147 after each stage of testing using methods of inspection adequate for applying the following criteria for defective:

(i) A leak resulting in a loss of 0.1% or more of the original amount of tritium or promethium-147 from the device;

(ii) Levels of radiation in excess of 0.5 millirad (5 microgray) per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber if the device contains promethium-147; and

(iii) Any other criteria specified in the license issued under this subsection.

d. No person licensed under this subsection shall transfer to persons generally licensed under 12VAC5-481-430 D or under an equivalent general license of the NRC or other agreement state:

(1) Any luminous safety device tested and found defective under any condition of a license issued under subdivisions 1 through 6 or this subdivision 8 of this subsection, unless the defective luminous safety device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

(2) Any luminous safety device contained within any lot that has been sampled and rejected as a result of the procedures in subdivision 8 b (2) of this subsection, unless:

(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under this subsection; and

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with subdivisions 8 b (2) and d (2) (i) of this subsection and any other criteria that may be required as a condition of the license issued under this subsection.

9. Transfer reports.

a. Each person licensed under this subsection shall file an annual report with the agency, which shall state the total quantity of tritium or promethium-147 transferred to persons generally licensed under 12VAC5-481-430 D. The report shall identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report shall cover the year ending June 30 and shall be filed within 30 days thereafter. If no transfers have been made to persons generally licensed under 12VAC5-481-430 D during the reporting period, the report shall indicate so.

b. Each person licensed under this subsection shall report annually all transfers of devices to persons for use under a general license in the NRC or another agreement state's regulations that are equivalent to 12VAC5-481-430 D to (i) the NRC at Director, Office of Nuclear Material Safety and Safeguards, ATTN: Document Control Desk/GLTS, by an appropriate method listed in 10 CFR 30.6(a) and (ii) the responsible agreement state agency. The report shall state the total quantity of tritium or promethium-147 transferred, identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. If no transfers have been made to the NRC or particular agreement

state during the reporting period, this information shall be reported to the NRC and responsible agreement state agency.

E. Special requirements for license to manufacture or initially transfer calibration sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under 12VAC5-481-430 F. An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under 12VAC5-481-430 F will be approved if:

1. The applicant satisfies the general requirement of 12VAC5-481-450 .

2. The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

a. Chemical and physical form and maximum quantity of americium 241 or radium-226 in the source;

b. Details of construction and design;

c. Details of the method of incorporation and binding of the americium-241 or radium-226 in the source;

d. Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

e. Details of quality control procedures to be followed in manufacture of the source;

f. Description of labeling to be affixed to the source or the storage container for the source; and

g. Any additional information, including experimental studies and tests, required by the NRC to facilitate a determination of the safety of the source.

3. Each source will contain no more than 5 microcuries of americium-241 or radium-226.

4. The agency determines, with respect to any type of source containing more than 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226, that:

a. The method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and

b. The source has been subjected to and has satisfactorily passed appropriate tests required by subdivision 5 of this subsection.

5. The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226 to tests as follows:

a. The initial quantity of radioactive material deposited on each source is measured by

direct counting of the source.

b. The sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226, such as physical handling, moisture, and water immersion.

c. The sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226 after each stage of testing using methods of inspection adequate for determining compliance with the criteria in subdivision 5 d of this subsection.

d. Source designs are rejected for which the following has been detected for any unit (i) removal of more than 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226 from the source or (ii) any other evidence of physical damage.

6. Labeling of devices. Each person licensed under this subsection shall affix to each source or storage container for the source a label that shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information in the following statement:

"The receipt, possession, use, and transfer of this source, Model, Serial No., are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission (NRC) or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

(Name of manufacturer or initial transferor)"

7. Leak testing of each source. Each person licensed under this subsection shall perform a dry wipe test upon each source containing more than 0.1 microcurie (3.7 kilobecquerel) of americium-241 or radium-226 before transferring the source to a general licensee under 12VAC5-481-430 F or under equivalent regulations of the NRC or another agreement state. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the filter paper shall be measured using methods capable of detecting 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226 by the methods described in this section, the source shall be rejected and shall not be transferred to a general licensee under 12VAC5-481-430 F, or equivalent regulations of the NRC or another agreement state.

F. Reserved.

G. Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license. An application for a specific license to manufacture or distribute radioactive material for use under the general license of 12VAC5-481-430 G will

be approved if:

1. The applicant satisfies the general requirements specified in 12VAC5-481-450 .

2. The radioactive material is to be prepared for distribution in prepackaged units of:

   a. Carbon-14 in units not exceeding 370 kBq (10 µCi) each.

   b. Cobalt-57 in units not exceeding 370 kBq (10 µCi) each.

   c. Hydrogen-3 (tritium) in units not exceeding 1.85 MBq (50 µCi) each.

   d. Iodine-125 in units not exceeding 370 kBq (10 µCi) each.

   e. Mock iodine-125 in units not exceeding 1.85 kBq (0.05 µCi) of iodine-129 and 185 Bq (0.005 µCi) of americium-241 each.

   f. Iodine-131 in units not exceeding 370 kBq (10 µCi) each.

   g. Iron-59 in units not exceeding 740 kBq (20 µCi) each.

   h. Selenium-75 in units not exceeding 370 kBq (10 µCi) each.

3. Each prepackaged unit bears a durable, clearly visible label:

   a. Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 370 kBq (10 µCi) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 1.85 MBq (50 µCi) of hydrogen-3 (tritium); 740 kBq (20 µCi) of iron-59; or mock iodine-125 in units not exceeding 1.85 kBq (0.05 µCi) of iodine-129 and 185 Bq (0.005 µCi) of americium-241 each; and

   b. Displaying the radiation caution symbol described in 12VAC5-481-850 and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals."

4. One of the following statements, as appropriate, or a substantially similar statement that contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure that accompanies the package:

   a. This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the Nuclear Regulatory Commission or of a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority.

   _____ Name of manufacturer

   b. This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical

or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a licensing state.

_____ Name of manufacturer

5. The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source shall also contain directions to the licensee regarding the waste disposal requirements set out in 12VAC5-481-910 .

H. Licensing the manufacture and distribution of ice detection devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under 12VAC5-481-430 H will be approved if:

1. The applicant satisfies the general requirements of 12VAC5-481-450;

2. The applicant submits sufficient information regarding each type of device pertinent to evaluation of the potential radiation exposure, including:

a. Chemical and physical form and maximum quantity of strontium-90 in the device;

b. Details of construction and design of the source of radiation and its shielding;

c. Radiation profile of a prototype device;

d. Procedures for and results of prototype testing of devices to demonstrate that the strontium-90 contained in each device will not be released or be removed from the device under the most severe conditions likely to be encountered in normal handling and use;

e. Details of quality control procedures to be followed in manufacture of the device;

f. Description of labeling to be affixed to the device;

g. Instructions for handling and installation of the device;

h. Any additional information, including experimental studies and tests, required by the agency to facilitate a determination of the safety of the device;

3. Each device will contain no more than 50 microcuries of strontium-90 in an insoluble form;

4. Each device will bear durable, legible labeling that includes the radiation caution symbol prescribed by 12VAC5-481-850 , a statement that the device contains strontium-90 and the quantity thereof, instructions for disposal and statements that the device may be possessed pursuant to a general license, that the manufacturer or civil authorities should be notified if the device is found, that removal of the labeling is prohibited, and that disassembly and repair of the device may be performed only by a person holding a specific license to

manufacture or service such devices;

5. The agency determines that:

a. The method of incorporation and binding of the strontium-90 in the device is such that the strontium-90 will not be released from the device under the most severe conditions that are likely to be encountered in normal use and handling of the device;

b. The strontium-90 is incorporated or enclosed so as to preclude direct physical contact by any individual with it and is shielded so that no individual will receive a radiation exposure to a major portion of his body in excess of 0.5 rem in a year under ordinary circumstances of use;

c. The device is so designed that it cannot be easily disassembled;

d. Prototypes of the device have been subjected to and have satisfactorily passed the tests required by subdivision 6 of this subsection;

e. Quality control procedures have been established to satisfy the requirements of subdivision 8 of this subsection;

6. The applicant shall subject at least five prototypes of the device to tests as follows:

a. The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of strontium-90, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

b. The devices are inspected for evidence of physical damage and for loss of strontium-90 after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in subdivision 6 c of this subsection.

c. Device designs are rejected for which the following has been detected for any unit:

(1) A leak resulting in a loss of 0.1% or more of the original amount of strontium-90 from the device;

(2) Surface contamination of strontium-90 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

(3) Any other evidence of physical damage;

7. The device has been registered in the Sealed Source and Device Registry; and

8. Quality assurance; prohibition of transfer.

a. Each person licensed under this subsection shall visually inspect each device and shall reject any that has an observable physical defect that could affect containment of the strontium-90.

b. Each person licensed under this subsection shall test each device for possible loss of strontium-90 or for contamination by wiping with filter paper an area of at least 100

square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The detection on the filter paper of more than 2,200 disintegrations per minute of radioactive material per 100 square centimeters of surface wiped shall be cause for rejection of the tested device.

c. Each person licensed under this subsection shall:

(1) Maintain quality assurance systems in the manufacture of the ice detection device containing strontium-90 in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

(2) Subject inspection lots to acceptance sampling procedures by procedures specified in subdivision 8 d of this subsection and in the license issued under this subsection, to provide at least 95% confidence that the lot tolerance percent defective of 5.0% will not be exceeded.

d. Each person licensed under this subsection shall subject each inspection lot to:

(1) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could possibly affect the effective containment of strontium-90, such as absolute pressure and water immersion.

(2) Inspection for evidence of physical damage, containment failure, or for loss of strontium-90 after each stage of testing using methods of inspection adequate to determine compliance with the following criteria for defective (i) a leak resulting in a loss of 0.1% or more of the original amount of strontium-90 from the device and (ii) any other criteria specified in the license issued under this subsection.

e. No person licensed under this subsection shall transfer to persons generally licensed under 12VAC5-481-430 H, or under an equivalent general license of the NRC or another agreement state:

(1) Any ice detection device containing strontium-90 tested and found defective under the criteria specified in a license issued under this subsection unless the defective ice detection device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

(2) Any ice detection device containing strontium-90 contained within any lot that has been sampled and rejected as a result of the procedures in subdivision 8 c (2) of this subsection, unless:

(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under this subsection; and

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with subdivisions 8 c (2) and 8 e (2) (i) of this subsection and any other criteria as may be required as a condition of the license issued under this subsection.

I. Manufacture, preparation, or transfer for commercial distribution of drugs containing

radioactive material for medical use under Part VII (12VAC5-481-1660 et seq.) of this chapter.

1. An application for a specific license to manufacture, prepare, or transfer for commercial distribution drugs containing radioactive material for use by persons authorized pursuant to Part VII (12VAC5-481-1660 et seq.) of this chapter will be approved if:

a. The applicant satisfies the general requirements specified in 12VAC5-481-450 ;

b. The applicant submits evidence that the applicant is at least one of the following:

(1) Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

(2) Registered or licensed with a state agency as a drug manufacturer;

(3) Licensed as a pharmacy by the Virginia Board of Pharmacy;

(4) Operating as a nuclear pharmacy within a federal medical institution; or

(5) A PET drug production facility registered with a state agency;

c. The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

d. The applicant satisfies the following labeling requirements:

(1) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol as described in 12VAC5-481-850 and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted.

(2) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol as described in 12VAC5-481-850 and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

2. A licensee authorized to manufacture, prepare or transfer for commercial distribution radioactive drugs shall ensure that any individual preparing the drugs is one of the following:

a. An authorized nuclear pharmacist (ANP) as defined in 12VAC5-481-10 ;

b. An individual who meets the requirements specified in 12VAC5-481-1770 and 12VAC5-481-1790 , and the licensee has received an approved license amendment identifying this individual as an ANP;

c. A pharmacist, as defined in 12VAC5-481-10 , designated as an ANP if:

(1) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material; and

(2) The individual practiced at a pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC; or

d. An individual under the supervision of an ANP as specified in 12VAC5-481-1710 .

3. Shall provide to the agency no later than 30 days after the date that the licensee allows, under subdivision 2 a or c of this subsection, the individual to work as an ANP:

a. The individual's certification by a specialty board whose certification process has been recognized by the NRC with the written attestation signed by a preceptor as required by 12VAC5-481-1770 ;

b. An NRC or another agreement state license;

c. NRC master materials licensee permit;

d. The permit issued by a licensee or NRC master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

e. Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

f. The Virginia Board of Pharmacy's license.

4. A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha, beta, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

a. Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

b. Check each instrument for constancy and proper operation at the beginning of each day of use.

5. Nothing in this subsection relieves the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

6. Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/ryubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination in accordance with 12VAC5-481-1930 . The licensee shall record the results of each test and retain each record for three years after the record is made.

J. Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Part VII (12VAC5-481-1660 et seq.) of this chapter for the medical use of radioactive material or use as a calibration, transmission or reference source will be approved if:

1. The applicant satisfies the general requirements in 12VAC5-481-450;

2. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

a. The radioactive material contained, its chemical and physical form, and amount;

b. Details of design and construction of the source or device;

c. Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;

d. For devices containing radioactive material, the radiation profile of a prototype device;

e. Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

f. Procedures and standards for calibrating sources and devices;

g. Legend and methods for labeling sources and devices as to their radioactive content; and

h. Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device provided, that instructions that are too lengthy for such label may be summarized on the label and printed in detail on a brochure that is referenced on the label;

3. The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the source or device is licensed by the agency for distribution to persons licensed pursuant to Part VII (12VAC5-481-1660 et seq.) of this chapter for the medical use

of radioactive material or under equivalent licenses of the NRC, or another agreement state, provided that such labeling for sources that do not require long-term storage may be on a leaflet or brochure that accompanies the source;

4. In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source;

5. In determining the acceptable interval for test of leakage of radioactive material, the agency will consider information that includes, but is not limited to:

a. Primary containment or source capsule;

b. Protection of primary containment;

c. Method of sealing containment;

d. Containment construction materials;

e. Form of contained radioactive material;

f. Maximum temperature withstood during prototype tests;

g. Maximum pressure withstood during prototype tests;

h. Maximum quantity of contained radioactive material;

i. Radiotoxicity of contained radioactive material; and

j. Operating experience with identical sources or devices or similarly designed and constructed sources or devices; and

6. The device has been registered in the Sealed Source and Device Registry.

K. Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass-volume applications.

1. An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 12VAC5-481-420 C or equivalent regulations of the NRC or another agreement state will be approved if:

a. The applicant satisfies the general requirements specified in 12VAC5-481-450;

b. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of 10% of the limits specified in 12VAC5-481-640; and

c. The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

2. In the case of an industrial product or device whose unique benefits are questionable, the agency will approve an application for a specific license under this subsection only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

3. The agency may deny any application for a specific license under this subsection if the end use or uses of the industrial product or device cannot be reasonably foreseen.

4. Each person licensed pursuant to subdivision 1 of this subsection shall:

a. Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

b. Label or mark each unit to:

(1) Identify the manufacturer or initial transferor of the product or device and the number of the license under which the product or device was manufactured or initially transferred, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

(2) State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the NRC or another agreement state;

c. Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

d. Do the following:

(1) Furnish a copy of the general license contained in 12VAC5-481-420 C and a copy of agency form "Certificate - Use of Depleted Uranium under a General License" to each person to whom depleted uranium in a product or device for use pursuant to the general license contained in 12VAC5-481-420 C is transferred; or

(2) Furnish a copy of the general license contained in the NRC's or another agreement state's regulation equivalent to 12VAC5-481-420 B and a copy of the NRC's or another agreement state's certificate, or alternatively, furnish a copy of the general license contained in 12VAC5-481-420 C and a copy of agency form "Certificate - Use of Depleted Uranium under a General License" to each person to whom depleted uranium in a product or device for use pursuant to the general license of the NRC or another agreement state is transferred, with a note explaining that use of the product or device

is regulated by the NRC or another agreement state under requirements substantially the same as those in 12VAC5-481-420 C;

e. Report to the agency all transfers of industrial products or devices to persons for use under the general license in 12VAC5-481-420 C. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under 12VAC5-481-420 C during the reporting period, the report shall so indicate;

f. Do the following:

(1) Report to the NRC all transfers of industrial products or devices to persons for use under the NRC general license in 10 CFR 40.25;

(2) For devices transferred to another agreement state, report to the responsible state agency all transfers of devices manufactured and distributed pursuant to this subsection for use under a general license in that state's regulations equivalent to 12VAC5-481-420 C;

(3) Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person;

(4) If no transfers have been made to NRC licensees during the reporting period, this information shall be reported to the NRC; and

(5) If no transfers have been made to general licensees within another agreement state during the reporting period, this information shall be reported to the responsible state agency upon the request of that agency; and keep records showing the name, address, and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 12VAC5-481-420 C or equivalent regulations of the NRC or another agreement state. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

L. Serialization of nationally tracked sources. Each licensee who manufactures a nationally tracked source shall assign a unique serial number to each nationally tracked source. Serial numbers shall be composed only of alpha-numeric characters.

12VAC5-481-490. Issuance of Specific Licenses.

A. Upon a determination that an application meets the requirements of the Act and the regulations of the agency, the agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

B. The agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this part as it deems appropriate or necessary in order to:

1. Minimize danger to public health and safety or property;

2. Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

3. Prevent loss or theft of material subject to this part.

12VAC5-481-500. Specific Terms and Conditions of Licenses.

A. Each license issued pursuant to this part shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the agency.

B. No license issued or granted under this part and no right to possess or utilize radioactive material granted by any license issued pursuant to this part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations, and orders of the agency, and shall give its consent in writing.

A request for license transfer shall include (i) the identity, technical, and financial qualifications of the proposed transferee and (ii) financial assurance for decommissioning information required under 12VAC5-481-450 C.

C. Each person licensed by the agency pursuant to this part shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

D. Each licensee shall notify the agency in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

E. Each licensee shall notify the agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

1. The licensee;

2. An entity (as that term is defined in 11 USC § 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

3. An affiliate (as that term is defined in 11 USC § 101(2)) of the licensee.

F. The notification specified in subsection E of this section shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

G. PET Distribution.

1. Authorization under 12VAC5-481-440 H to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other state or local requirements governing radioactive drugs.

2. Each licensee authorized under 12VAC5-481-440 H to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

a. Satisfy the labeling requirements in 12VAC5-481-480 I 1 d for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

b. Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in 12VAC5-481-480 I 3.

3. A licensee that is a pharmacy authorized under 12VAC5-481-440 H to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

a. An ANP that meets the requirements in 12VAC5-481-480 I 2; or

b. An individual under the supervision of an ANP as specified in 12VAC5-481-1710 .

4. A pharmacy, authorized under 12VAC5-481-440 H to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an ANP, shall meet the requirements of 12VAC5-481-480 I 2.

12VAC5-481-510. Expiration and Termination of Licenses and Decommissioning of Sites and Separate Building or Outdoor Areas.

A. Except as provided in 12VAC5-481-520 , a specific license shall expire at the end of the specified day in the month and year stated in the license. If an application for license renewal has been filed at least 30 days prior to the expiration date stated in the existing license and the agency denies the renewal application, the license shall expire on the date as stated in the determination of denial. If an application for license renewal is filed less than 30 days from the expiration date stated in the existing license, the agency may deny the renewal application and the license shall expire on the expiration date stated in the license.

B. A specific license revoked by the agency expires at the end of the day on the date of the agency's final determination, or on the expiration date stated in the determination, or as otherwise provided by an agency order.

C. A specific license remains valid, with respect to possession of radioactive material, until the agency notifies the licensee in writing that the license is terminated. While the license is valid, the licensee shall do all of the following:

1. Limit actions involving radioactive material to those related to decommissioning and other activities related to preparation for release for unrestricted use.

2. Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the agency notifies the licensee in writing that the license is terminated.

D. A licensee shall do all of the following:

1. Notify the agency within 60 days of any of the following:

a. Expiration of the license pursuant to subsections A or B of this section.

b. The licensee's deciding to permanently cease principal activities at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with agency requirements.

c. The absence of conduct of any principal activities under the license for a period of 24 months.

d. The absence of conduct of any principal activities for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with agency requirements.

2. If any separate building or outdoor area contains residual radioactivity so that the building or outdoor area is unsuitable for release, do one of the following:

a. Begin decommissioning its site, separate building or outdoor area if a decommissioning plan has been previously approved by the agency.

b. Submit a decommissioning plan within 12 months if required by subsection F of this section and begin decommissioning upon approval of that plan.

E. Concurrent with the notification required by subsection D of this section, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to 12VAC5-481-450 C in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance shall be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to subdivision H 5 of this section. Following approval of the decommissioning plan and with the agency's approval, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site.

F. A licensee shall submit a decommissioning plan to the agency if required by license

condition or if the procedures and activities necessary to carry out decommissioning of the site, separate building or outdoor area have not been previously approved by the agency and the procedures and activities may adversely effect the health and safety of workers or the public. The procedures may not be carried out prior to the agency's approval of the decommissioning plan. Examples of applicable procedures and activities include any of the following cases:

1. Procedures that would involve techniques not applied routinely during cleanup or maintenance operations.

2. Procedures by which workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation.

3. Procedures that could result in significantly greater airborne concentrations of radioactive materials than are present during operation.

4. Procedures that could result in significantly greater releases of radioactive material to the environment than those associated with operation.

G. The agency may approve an alternate schedule for submittal of a decommissioning plan required pursuant to subsection D of this section if the agency determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

H. The proposed decommissioning plan for the site or separate building or outdoor area shall include all of the following elements:

1. A description of the conditions of the site, separate building or outdoor area sufficient to evaluate the acceptability of the plan.

2. A description of planned decommissioning activities.

3. A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning.

4. A description of the planned final radiation survey.

5. An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

6. For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, a justification for the delay based on the criteria in subsection J of this section.

I. Except as provided in subsection H of this section, a licensee shall complete decommissioning of the site or separate building or outdoor area no later than 24 months following the initiation of decommissioning. When decommissioning involves the entire site,

a licensee shall request license termination no later than 24 months following the initiation of decommissioning.

J. The agency may approve a request for an alternative schedule for completion of decommissioning of the site, separate building or outdoor area, and license termination if appropriate, if the agency determines that the alternative is warranted after consideration of all the following:

1. Whether it is technically feasible to complete decommissioning within the allotted 24-month period.

2. Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period.

3. Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay.

4. Whether a significant reduction in radiation exposure to workers may be achieved by allowing short-lived radionuclides to decay.

5. Other site-specific factors which the agency may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, court decisions, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

K. As the final step in decommissioning, a licensee shall do all the following:

1. Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed agency form for disposition of radioactive materials or equivalent information.

2. Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 12VAC5-481-1161 .

3. Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels per 100 square centimeters, disintegrations per minute per 100 square centimeters or microcuries per 100 square centimeters - removable and fixed - for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete.

4. Specify the survey instruments used and certify that each instrument is properly calibrated and tested.

L. The agency shall terminate a specific license, including an expired license, by written notice to the licensee when the agency determines all of the following have occurred:

1. Radioactive material has been properly disposed of.

2. Reasonable effort has been made to eliminate residual radioactive contamination, if present.

3. The licensee has filed with the agency sufficient information, including a radiation survey, to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 12VAC5-481-1161 .

4. The licensee has submitted records required under 12VAC5-481-571 to the agency.

12VAC5-481-520. Renewal of Licenses.

A. Applications for renewal of specific licenses shall be filed in accordance with 12VAC5-481-440 .

B. In any case in which a licensee, not less than 30 days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the agency.

12VAC5-481-530. Amendment of Licenses at Request of Licensee.

Amendment requests for a license shall be filed in accordance with 12VAC5-481-440 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

12VAC5-481-540. Agency Action on Applications to Renew or Amend.

In considering an application by a licensee to renew or amend the license, the agency will apply the criteria set forth in 12VAC5-481-450 through 12VAC5-481-480 and in Parts V (12VAC5-481-1170 et seq.), VII (12VAC5-481-1660 et seq.), XI (12VAC5-481-2330 et seq.), XII (12VAC5-481-2660 et seq.), XIV (12VAC5-481-3140 et seq.), or XVI (12VAC5-481-3460 et seq.) of this chapter, as applicable.

12VAC5-481-550. Persons Possessing a License for Source, Byproduct, or Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass on Effective Date of These Regulations.

Article 5. Licenses Held at the Time of the Effective Date of These Regulations

Any person who, on the effective date as stated in 12VAC5-481-160 , possesses a general or specific license for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass, issued by the NRC, shall be deemed to possess a like license issued under this part and the Act, such license to expire either 90 days after receipt from the agency of a notice of expiration of such license, or on the date or expiration specified in the NRC license, whichever is earlier.

12VAC5-481-560. Persons Possessing Narm on Effective Date of These Regulations.

Any person who, on September 20, 2006, possesses NARM for which a specific license is required by the Act or this part shall be deemed to possess such a license issued under the Act and this part. Such license shall expire 90 days after September 20, 2006; provided, however, that if within the 90 days the person possessing such material files an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the agency.

12VAC5-481-570. Transfer of Material.

Article 6. Transfer of Material

A. No licensee shall transfer radioactive material except as authorized pursuant to this section.

B. Except as otherwise provided in the license and subject to the provisions of subsections C and D of this section, any licensee may transfer radioactive material:

1. To the agency only after receiving prior approval from the agency.

2. To the United States Department of Energy;

3. To any person exempt from these regulations to the extent permitted under such exemption;

4. To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the agency, the NRC, or another agreement state, or to any person otherwise authorized to receive such material by the federal government or any agency thereof, the agency, or another agreement state; or

5. As otherwise authorized by the agency in writing.

C. Before transferring radioactive material to a specific licensee of the agency, the NRC, or another agreement state, or to a general licensee who is required to register with the agency, the NRC, or another agreement state prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

D. Any of the following methods for the verification required by subsection C of this section is acceptable:

1. The transferor may possess and read a current copy of the transferee's specific license or registration certificate.

2. The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date.

3. For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type,

form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided that the oral certification is confirmed in writing within 10 days.

4. The transferor may obtain other information compiled by a reporting service from official records of the agency, the NRC, or another agreement state, regarding the identity of licensees and the scope and expiration dates of licenses and registration.

5. When none of the methods of verification described in subdivisions 1 through 4 of this subsection are readily available or when a transferor desires to verify that information received by one of such methods is correct or up to date, the transferor may obtain and record confirmation from the agency, the NRC, or another agreement state, that the transferee is licensed to receive the radioactive material.

E. Shipment and transport of radioactive material shall be in accordance with the provisions of Part XIII (12VAC5-481-2950 et seq.) of this chapter.

12VAC5-481-571. Receipt, Transfer and Disposal Records.

Article 7. Records

A. Record retention. A licensee shall retain records required by 12VAC5-481-100 or by license condition. If a retention period is not otherwise specified by this chapter or license condition, the record shall be retained until the agency terminates each license.

B. Transfer of records to the agency. Prior to license termination, a licensee authorized to possess radioactive material, in an unsealed form, with a half-life greater than 120 days, shall forward to the agency all records of disposal of licensed material made under 12VAC5-481-910 to 12VAC5-481-950 , including burials authorized before January 28, 1981, and the results of measurements and calculations required by 12VAC5-481-1000 .

C. Transfer of records to new licensee.

1. If licensed activities are transferred or assigned in accordance with 12VAC5-481-570 , each licensee authorized to possess radioactive material in unsealed form, with a half-life greater than 120 days, shall transfer the following records to the new licensee:

a. Records of disposal of licensed material made under 12VAC5-481-910 to 12VAC5-481-950 , including burials authorized before January 28, 1981.

b. Records of the results of measurements and calculations required by12VAC5-481-1000.

2. The new licensee shall be responsible for maintaining the records required in subdivision C 1 of this section until the license is terminated.

D. Transfer of records of decommissioning activities. A licensee shall forward the records required by 12VAC5-481-450 C to the agency prior to license termination.

12VAC5-481-580. Modification and Revocation of Licenses.

Article 8. Modification and Revocation of Licenses

A. The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act, or by reason of rules, regulations, and orders issued by the agency.

B. Any license may be revoked, suspended, or modified, in whole or in part, for any false statement in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means that would warrant the agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule, regulation, or order of the agency.

C. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct that may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

12VAC5-481-590. Reciprocal Recognition of Licenses.

Article 9. Reciprocity

Licenses of radioactive, source, and special nuclear material in quantities not sufficient to form a critical mass.

1. Subject to these regulations, any person who holds a specific license from the NRC or another agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within the Commonwealth for a period not in excess of 180 days during the one-year reciprocal approval period, provided that:

    a. The licensing document does not limit the activity authorized by such document to specified installations or locations;

    b. The out-of-state licensee notifies the agency in writing at least three days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in this subdivision;

    c. The out-of-state licensee complies with all applicable regulations of the agency and with all the terms and conditions of the licensing document, except any such terms and conditions that may be inconsistent with applicable regulations of the agency;

d. The out-of-state licensee supplies such other information as the agency may request;

e. The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this subdivision except by transfer to a person:

(1) Specifically licensed by the agency, the NRC or another agreement state to receive such material, or

(2) Exempt from the requirements for a license for such material under 12VAC5-481-400 A; and

f. The out-of-state licensee submits the payment required by 12VAC5-490-40 to the agency.

2. Notwithstanding the provisions of subdivision 1 of this section, any person who holds a specific license issued by the NRC or another agreement state authorizing the holder to manufacture, transfer, install, or service a device described in 12VAC5-481-430 B within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state provided that:

a. Such person shall file a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

b. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the NRC or another agreement state;

c. Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

d. The holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in 12VAC5-481-430 B or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

3. The agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the NRC or another agreement state, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

12VAC5-481-600. Purpose.

Part IV. Standards For Protection Against Radiation

Article 1. General Provisions

A. Part IV (12VAC5-481-600 et seq.) of this chapter establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the agency. These regulations are issued pursuant to the Act, as amended.

B. The requirements of Part IV (12VAC5-481-600 et seq.) of this chapter are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in Part IV (12VAC5-481-600 et seq.) of this chapter. However, nothing in Part IV (12VAC5-481-600 et seq.) of this chapter shall be construed as limiting actions that may be necessary to protect health and safety in an emergency.

12VAC5-481-610. Scope.

Except as specifically provided in other parts of these regulations, Part IV (12VAC5-481-600 et seq.) of this chapter applies to persons licensed or registered by the agency to receive, possess, use, transfer, or dispose of sources of radiation. The limits in Part IV (12VAC5-481-600 et seq.) of this chapter do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs.

12VAC5-481-620. Implementation.

A. Any existing license or registration condition that is more restrictive than Part IV (12VAC5-481-600 et seq.) of this chapter remains in force until there is an amendment or renewal of the license or registration.

B. If a license or registration condition exempts a licensee or registrant from a provision of Part IV (12VAC5-481-600 et seq.) of this chapter in effect on or before September 20, 2006, it also exempts the licensee or registrant from the corresponding provision of Part IV (12VAC5-481-600 et seq.) of this chapter.

C. If a license or registration condition cites provisions of Part IV (12VAC5-481-600 et seq.) of this chapter in effect prior to September 20, 2006, which do not correspond to any provisions of Part IV (12VAC5-481-600 et seq.) of this chapter, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

12VAC5-481-630. Radiation Protection Programs.

Article 2. Radiation Protection Programs

A. Each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this chapter.

B. The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

C. The licensee shall periodically (not to exceed 12 months) review the radiation protection program content and implementation.

D. To implement the ALARA requirements of subsection B of this section, and notwithstanding the requirements of 12VAC5-481-720 , a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, shall be established by licensees such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in 12VAC5-481-1110 and promptly take appropriate corrective action to ensure against recurrence.

12VAC5-481-640. Occupational Dose Limits for Adults.

Article 3. Occupational Dose Limits

A. The licensee shall control the occupational dose to individual adults, except for planned special exposures under 12VAC5-481-690 , to the following dose limits.

1. An annual limit, which is the more limiting of:

    a. The total effective dose equivalent being equal to 5 rem (0.05 Sv); or

    b. The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rem (0.5 Sv).

2. The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

    a. A lens dose equivalent of 15 rem (0.15 Sv), and

    b. A shallow-dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

B. Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime in accordance with 12VAC5-481-690 A 5.

C. When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent shall be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the agency. The assigned deep-dose equivalent shall be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent shall be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be

assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits if the individual monitoring device was not in the region of highest potential exposure or the results of individual monitoring are unavailable.

D. Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Appendix B to 10 CFR Part 20 and may be used to determine the individual's dose (see 12VAC5-481-1040) and to demonstrate compliance with the occupational dose limits.

E. In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity (see Appendix B to 10 CFR Part 20).

F. The licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person (see 12VAC5-481-1020).

12VAC5-481-650. Compliance with Requirements for Summation of External and Internal Doses.

A. If the licensee is required to monitor under subdivisions 1 and 2 of 12VAC5-481-760 , the licensee shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee is required to monitor only under subdivision 1 of 12VAC5-481-760 or only under subdivision 2 of 12VAC5-481-760 , then summation is not required to demonstrate compliance with the dose limits. The licensee may demonstrate compliance with the requirements for summation of external and internal doses by meeting one of the conditions specified in subsections B, C, and D of this section. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

B. Intake by inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep-dose equivalent divided by the total effective dose equivalent limit and one of the following does not exceed unity:

1. The sum of the fractions of the inhalation ALI for each radionuclide,

2. The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or

3. The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For the purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors and the committed dose equivalent per unit intake is greater than 10% of the maximum weighted value of the committed dose equivalent per unit intake of any organ or tissue.

C. Intake by oral ingestion. If the occupationally exposed individual also receives an intake of

radionuclides by oral ingestion greater than 10% of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.

D. Intake through wounds or absorption through skin. The licensee shall evaluate and to the extent practical account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated.

12VAC5-481-660. Determination of External Dose from Airborne Radioactive Material.

A. Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep-dose equivalent, lens dose equivalent, and shallow-dose equivalent from external exposure to the radioactive cloud (see Appendix B to 10 CFR Part 20).

B. Airborne radioactive measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive materials includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

12VAC5-481-670. Determination of Internal Exposure.

A. For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required under 12VAC5-481-760 , take suitable and timely measurements of either:

1. Concentrations of radioactive materials in air in work areas;

2. Quantities of radionuclides in the body;

3. Quantities of radionuclides excreted from the body; or

4. Combinations of these measurements.

B. Unless respiratory protective equipment is used as provided in 12VAC5-481-830 or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

C. When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior or the material in an individual is known, the licensee may:

1. Use that information to calculate the committed effective dose equivalent, and if used, the licensee shall document that information in the individual's record;

2. Upon prior approval from the agency, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material (e.g., aerosol size distribution or density); and

3. Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of

a given radionuclide (see Appendix B to 10 CFR Part 20) to the committed effective dose equivalent.

D. If the licensee chooses to assess intakes of Class Y material using the measurements given in subdivision A 2 or A 3 of this section, the licensee may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by 12VAC5-481-1100 or 12VAC5-481-1110 , in order to permit the licensee to make additional measurements basic to the assessments.

E. If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

1. The sum of the ratios of the concentration to the appropriate DAC value (e.g., D, W, or Y) from Appendix B to 10 CFR Part 20 for each radionuclide in the mixture; or

2. The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

F. If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

G. When a mixture of radionuclides in air exists, licensees may disregard certain radionuclides in the mixture if:

1. The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in 12VAC5-481-640 and in complying with the monitoring requirements in 12VAC5-481-760 A 2,

2. The concentration of any radionuclide disregarded is less than 10% of its DAC, and

3. The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30%.

H. When determining the committed effective dose equivalent, the following information may be considered:

1. In order to calculate the committed effective dose equivalent, the licensee may assume that the inhalation of one ALI or an exposure of 2,000 DAC-hours results in a committed effective dose equivalent of 5 rem (0.05 Sv) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

2. When the ALI and the associated DAC is determined by the nonstochastic organ dose limit of 50 rem (0.5 Sv), the intake of radionuclides that would result in a committed effective dose equivalent of 5 rem (0.05 Sv) (the stochastic ALI) is listed in parentheses of Appendix B to 10 CFR Part 20. In this case, the licensee may, as a simplifying assumption, use the stochastic ALIs to determine committed effective dose equivalent. However, if the licensee uses the stochastic ALIs, the licensee shall also demonstrate that the limit in 12VAC5-481-640 A 1 (b) is met.

12VAC5-481-680. Determination of Prior Occupational Dose.

A. For each individual who may enter the licensee's or registrant's restricted area and is likely to receive, in a year, an occupational dose requiring monitoring pursuant to 12VAC5-481-760 , the licensee or registrant shall determine the occupational radiation dose received during the current year.

B. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

1. The internal and external doses from all previous planned special exposures; and

2. All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual.

C. In complying with the requirements of subsection A or B of this section, a licensee or registrant may:

1. Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year;

2. Accept, as the record of lifetime cumulative radiation dose, an up-to-date occupational radiation exposure form provided by the agency or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and

3. Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

D. Do the following:

1. The licensee or registrant shall record the exposure history, as required by this section on an occupational radiation exposure form provided by the agency, or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing the occupational radiation exposure form provided by the agency or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on the occupational radiation exposure form provided by the agency or equivalent indicating the periods of time for which data are not available.

2. Licensees or registrants are not required to partition historical dose between external dose equivalent(s) and internal committed dose equivalent(s). Further, occupational exposure histories obtained and recorded on the occupational radiation exposure form provided by the agency or equivalent before September 20, 2006, might not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

E. If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

1. In establishing administrative controls pursuant to 12VAC5-481-640 for the current year, that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

2. That the individual is not available for planned special exposures.

F. The licensee or registrant shall retain the records on an occupational radiation exposure form provided by the agency or equivalent until the agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing the occupational radiation exposure form provided by the agency or equivalent for three years after the record is made.

12VAC5-481-690. Planned Special Exposures.

A licensee may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in 12VAC5-481-640 provided that each of the following conditions is satisfied:

1. The licensee authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical.

2. The licensee, and employer if the employer is not the licensee, specifically authorizes the planned special exposure in writing before the exposure occurs.

3. Before a planned special exposure, the licensee ensures that each individual involved is:

a. Informed of the purpose of the planned operation;

b. Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

c. Instructed in the measure to be taken to keep the dose ALARA considering other risks that may be present.

4. Prior to permitting an individual to participate in a planned special exposure, the licensee ascertains prior doses as required by 12VAC5-481-1020 during the lifetime of the individual for each individual involved.

5. Subject to 12VAC5-481-640 A 2, the licensee does not authorize a planned special

exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

a. The numerical values of any of the dose limits in 12VAC5-481-640 A 1 in any year; and

b. Five times the annual dose limits in 12VAC5-481-640 A 1 during the individual's lifetime.

6. The licensee maintains records of the conduct of a planned special exposure in accordance with 12VAC5-481-1030 and submits a written report in accordance with 12VAC5-481-1120 .

7. The licensee records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual in writing of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures is not be considered in controlling future occupational dose limits of the individual under 12VAC5-481-640 A 1 but is to be included in evaluations required by subdivisions 4 and 5 of this section.

12VAC5-481-700. Occupational Dose Limits for Minors.

The annual occupational dose limits for minors are 10% of the annual dose limits specified for adult workers in 12VAC5-481-640 .

12VAC5-481-710. Dose to an Embryo/Fetus.

A. The licensee shall ensure that the dose equivalent to the embryo/fetus during the entire pregnancy due to occupational exposure of a declared pregnant woman does not exceed 500 millirem (5 mSv).

B. The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limits in subsection A of this section.

C. The dose equivalent to the embryo/fetus is the sum of:

1. The deep dose equivalent to the declared pregnant woman; and

2. The dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

D. If the dose equivalent to the embryo/fetus is found to have exceeded 500 millirem (5 mSv), or is within 50 millirem (0.5 mSv) of this dose, by the time the woman declares the pregnancy to the licensee, the licensee shall be deemed to be in compliance with subsection A of this section if the additional dose equivalent to the embryo/fetus does not exceed 50 millirem (0.5 mSv) during the remainder of the pregnancy.

12VAC5-481-720. Dose Limits for Individual Members of the Public.

Article 4. Radiation Dose Limits for Individual Members of the Public

A. Each licensee shall conduct operations so that:

1. The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 100 millirem (1 mSv) in a year exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under 12VAC5-481-1870 , from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with 12VAC5-481-930; and

2. The dose in any unrestricted area from external sources exclusive of the dose contribution from individuals administered radioactive material and released in accordance with 12VAC5-481-1870 does not exceed 2 millirem (0.02 millisievert) in any one hour.

B. If the licensee permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

C. Notwithstanding subdivision A 1 of this section, a licensee may permit visitors to an individual who cannot be released under 12VAC5-481-1870 to receive a radiation dose greater than 100 millirem (1 mSv) if:

1. The radiation dose received does not exceed 500 millirem (5 mSv); and

2. The authorized user as defined in 12VAC5-481-10 has determined before the visit that it is appropriate.

D. A licensee or licensee applicant may apply for prior agency authorization to operate up to an annual dose limit for an individual member of the public of 500 millirem (5 mSv). The licensee or license applicant shall include the following information in this application:

1. Demonstration of the need for and the expected duration of operations in excess of the limit in subsection A of this section;

2. The licensee's program to assess and control dose within the 500 millirem (5 mSv) annual limit; and

3. The procedures to be followed to maintain the dose as low as is reasonably achievable.

E. In addition to these requirements, a licensee subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR Part 190 shall comply with those standards.

F. The agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

12VAC5-481-730. Compliance with Dose Limits for Individual Members of the Public.

A. The licensee shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in 12VAC5-481-720 .

B. A licensee shall show compliance with the annual dose limits in 12VAC5-481-720 by:

1. Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual dose limit; or

2. Demonstrating that:

a. The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table 2 of Appendix B to 10 CFR Part 20; and

b. If an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 2 millirem (0.02 mSv) in an hour and 50 millirem (0.5 mSv) in a year.

C. Upon approval from the agency, the licensee may adjust the effluent concentration values in Table 2 of Appendix B to 10 CFR Part 20, for members of the public, to take into account the actual physical and chemical characteristics of the effluents (e.g., aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form).

12VAC5-481-740. Testing for Leakage or Contamination of Sealed Sources.

Article 5. Testing for Leakage or Contamination of Sealed Sources

A. The licensee or registrant in possession of any sealed source shall assure that:

1. Each sealed source, except as specified in subsection B of this section, is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee or registrant has a certificate from the transferor indicating that the sealed source was tested within six months before transfer to the licensee or registrant;

2. Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed six months or at alternative intervals approved by the agency, after evaluation of information specified by 12VAC5-481-480 J 4 and 5, the NRC or another agreement state;

3. Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three months or at alternative intervals approved by the agency, after evaluation of information specified by 12VAC5-481-480 J 4 and 5, the NRC or another agreement state;

4. For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or

might be leaking, the licensee or registrant shall assure that the sealed source is tested for leakage or contamination before further use;

5. Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of 185 Bq (0.005 µCi) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position;

6. The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 37 Bq (0.001 µCi) of radon-222 in a 24-hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume and time;

7. Tests for contamination from radium daughters shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 185 Bq (0.005 µCi) of a radium daughter which has a half-life greater than four days.

B. A licensee or registrant need not perform test for leakage or contamination on the following sealed sources:

1. Sealed sources containing only radioactive material with a half-life of less than 30 days;

2. Sealed sources containing only radioactive material as a gas;

3. Sealed sources containing 3.7 MBq (100 µCi) or less of beta or photon-emitting material or 370 kBq (10 µCi) or less of alpha-emitting material;

4. Sealed sources containing only hydrogen-3;

5. Seeds of iridium-192 encased in nylon ribbon; and

6. Sealed sources that are stored, not being used and identified as in storage. The licensee or registrant shall, however, test each such sealed source for leakage or contamination and receive the test results at intervals not to exceed five years and within six months before the date of use or transfer.

C. Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the agency, the NRC or another agreement state to perform such services.

D. Test results shall be kept in units of becquerel or microcurie and maintained for inspection by the agency. Records of test results for sealed sources shall be made pursuant to 12VAC5-481-1010 .

E. The following shall be considered evidence that a sealed source is leaking:

1. The presence of 185 Bq (0.005 µCi) or more of removable contamination on any test sample;

2. Leakage of 37 Bq (0.001 µCi) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium;

3. The presence of removable contamination resulting from the decay of 185 Bq (0.005 µCi) or more of radium.

F. The licensee or registrant shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this part.

G. Reports of test results for leaking or contaminated sealed sources shall be made pursuant to 12VAC5-481-1150 .

12VAC5-481-750. General.

Article 6. Surveys and Monitoring

A. Licensees shall make or cause to be made surveys of areas, including the subsurface, that:

1. Are necessary for the licensee to comply with this chapter; and

2. Are reasonable under the circumstances to evaluate:

a. The magnitude and extent of radiation levels;

b. The concentrations or quantities of radioactive material; and

c. The potential radiological hazards of the radiation levels and residual radioactivity detected.

B. Notwithstanding 12VAC5-481-1000 A, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site shall be kept with records important for decommissioning, and such records shall be retained in accordance with 12VAC5-481-450 C 8.

C. Licensees shall ensure that the survey instruments used to show compliance with this chapter are calibrated before first use, annually (not to exceed 12 months), except when a more frequent interval is specified in another applicable part of this chapter or a license condition, and following a repair that affects the calibration. These calibrations shall include:

1. Use of a radiation source on all scales;

2. At energies appropriate for the use;

3. For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at three points between 2 and 1000 mrem (0.02 and 10 millisieverts) per hour;

4. For dose rate instruments, so that an accuracy within plus or minus 20% of the true radiation dose can be demonstrated at each point checked; and

5. Conspicuously note on the instrument the date of calibration.

D. Licensees may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20%.

E. All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities, that require processing to determine the radiation dose and that are used by the licensee to comply with 12VAC5-481-640 , with other applicable provisions of this chapter, or with conditions specified in a license shall be processed and evaluated by a dosimetry processor with the following:

1. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

2. Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiation for which the individual wearing the dosimeter is monitored.

12VAC5-481-760. Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.

Each licensee shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this part. At a minimum:

1. Each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by:

a. Adults likely to receive, in one year from sources external to the body, a dose in excess of 10% of the limits in 12VAC5-481-640 A;

b. Minors likely to receive, in one year from radiation sources external to the body, a deep dose equivalent in excess of 100 millirem (1 mSv), a lens dose equivalent in excess of 150 millirem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 500 millirem (5 mSv);

c. Declared pregnant women likely to receive, during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 100 millirem (1 mSv); and

d. Individuals entering a high or very high radiation area.

2. Each licensee shall monitor (see 12VAC5-481-670) the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

a. Adults likely to receive, in one year, an intake in excess of 10% of the applicable ALIs in Table 1, Columns 1 and 2, of Appendix B to 10 CFR Part 20;

b. Minors likely to receive, in one year, a committed effective dose equivalent in excess of 100 millirem (1 mSv); and

c. Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 100 millirem (1 mSv).

12VAC5-481-770. Location of Individual Monitoring Devices.

Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with 12VAC5-481-760 wear individual monitoring devices as follows:

1. An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar);

2. An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman, pursuant to 12VAC5-481-710 , shall be located at the waist under any protective apron being worn by the woman;

3. An individual monitoring device used for monitoring the eye dose equivalent, to demonstrate compliance with 12VAC5-481-640 , shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye;

4. An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with 12VAC5-481-640 , shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

12VAC5-481-780. Control of Access to High Radiation Areas.

Article 7. Control of Exposure from External Sources in Restricted Areas

A. The licensee shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

1. A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 100 millirem (1 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates;

2. A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of entry; or

3. Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

B. In place of the controls required by subsection A of this section for a high radiation area, the licensee may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

C. A licensee may apply to the agency for approval of alternative methods for controlling access to high radiation areas.

D. The licensee shall establish the controls required by subsections A and C of this section in a way that does not prevent individuals from leaving a high radiation area.

E. Control is not required for each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with regulations of the U.S. Department of Transportation provided that:

1. The packages do not remain in the area longer than three days; and

2. The dose rate at one meter from the external surface of any package does not exceed 10 millirem (0.1 mSv) per hour.

F. Control of entrance or access to rooms or other areas in hospitals is not required solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who will take the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the limits established in this part and to operate within the ALARA provisions of the licensee's radiation protection program.

G. The licensee or registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in this section if the licensee or registrant has met all the specific requirements for access and control specified in other applicable parts of this chapter, such as Part V (12VAC5-481-1170 et seq.) for industrial radiography, Part VI (12VAC5-481-1580 et seq.) for X-rays in the healing arts, Part IX (12VAC5-481-2140 et seq.) for particle accelerators, and Part XII (12VAC5-481-2660 et seq.) for irradiators.

12VAC5-481-790. Control of Access to Very High Radiation Areas.

A. In addition to the requirements in 12VAC5-481-780 , the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 5 Gy (500 rad) or more in one hour at one meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic X-ray systems are the only source of radiation, or to nonself-shielded irradiators.

B. The licensee or registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in subsection A of this section if the registrant has met all the specific requirements for access and control specified in other applicable parts of these regulations, such as Part V (12VAC5-481-1170 et seq.) for industrial radiography, Part VI (12VAC5-481-1580 et seq.) for X-rays in the healing arts, Part IX (12VAC5-481-2140 et seq.) for particle

accelerators, and Part XII (12VAC5-481-2660 et seq.) for irradiators.

12VAC5-481-800. (Repealed.)

12VAC5-481-810. Use of Process or Other Engineering Controls.

Article 8. Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas

The licensee shall use, to the extent practical, process or other engineering controls (e.g., containment, decontamination, or ventilation) to control the concentration of radioactive material in air.

12VAC5-481-820. Use of Other Controls.

A. When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in the air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

1. Control of access;

2. Limitation of exposure times;

3. Use of respiratory protection equipment; or

4. Other controls.

B. If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on the industrial health and safety of workers.

12VAC5-481-830. Use of Individual Respiratory Protection Equipment.

A. If the licensee assigns or permits the use of respiratory protection equipment to limit the intake of radioactive material:

1. The licensee shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health (NIOSH) except as otherwise noted in this part.

2. If the licensee wishes to use equipment that has not been tested or certified by NIOSH, or for which there is no schedule for testing or certification, the licensee shall submit an application to the agency for authorized use of this equipment except as provided in this part. The application shall include evidence that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use. This shall be demonstrated either by licensee testing or on the basis of reliable test information.

3. The licensee shall implement and maintain a respiratory protection program that includes:

a. Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;

b. Surveys and bioassays, as necessary, to evaluate actual intakes;

c. Testing of respirators for operability (i.e., user seal check for face sealing devices and functional check for others) immediately prior to each use;

d. Written procedures regarding:

(1) Monitoring, including air sampling and bioassays;

(2) Supervision and training of respirator users;

(3) Fit testing;

(4) Respirator selection;

(5) Breathing air quality;

(6) Inventory and control;

(7) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;

(8) Recordkeeping; and

(9) Limitations on periods of respirator use and relief from respirator use;

e. Determination by a physician that the individual user is medically fit to use respiratory protection equipment at the following stages:

(1) Before the initial fitting of a face sealing respirator;

(2) Before the first field use of non-face sealing respirators, and

(3) Either every 12 months thereafter, or periodically at a frequency determined by a physician; and

f. Fit testing, with fit factor greater than 10 times the assigned protection factor (APF) for negative pressure devices, and a fit factor greater than 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed one year. Fit testing shall be performed with the facepiece operating in the negative pressure mode.

4. The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

5. The licensee shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

6. Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment, are used from which an unaided individual would have difficulty extricating himself. The standby persons shall be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers (e.g., visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons shall be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

7. Atmosphere-supplying respirators shall be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997, and included in the regulations of the Occupational Safety and Health Administration (29 CFR 1910.134(i)(1)(ii)(A) through (E). Grade D quality air criteria include:

a. Oxygen content (v/v) of 19.5-23.5%;

b. Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;

c. Carbon monoxide (CO) content of 10 ppm or less;

d. Carbon dioxide content of 1,000 ppm or less; and

e. Lack of noticeable odor.

8. The licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face (facepiece seal or valve function) and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

9. In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value shall be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

B. The agency may impose restrictions in addition to the provisions of this section, 12VAC5-481-820 , and 12VAC5-481-3680 in order to:

1. Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

2. Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

C. The licensee shall obtain authorization from the agency before using assigned protection factors in excess of those specified in 12VAC5-481-3680 . The agency may authorize a licensee to use higher assigned protection factors on receipt of an application that:

1. Describes the situation for which a need exists for higher protection factors; and

2. Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

12VAC5-481-840. Security and Control of Licensed or Registered Sources of Radiation.

Article 9. Security and Control of Licensed or Registered Sources of Radiation

A. The licensee shall:

1. Secure radioactive material from unauthorized removal or access when stored in controlled or unrestricted areas.

2. Control and maintain constant surveillance and use devices or administrative procedures to prevent unauthorized use of radioactive material that is in a controlled or unrestricted area and that is not in storage.

B. The registrant shall secure registered radiation machines from unauthorized removal.

C. The registrant shall use devices or administrative procedures to prevent unauthorized use of registered radiation machines.

D. Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

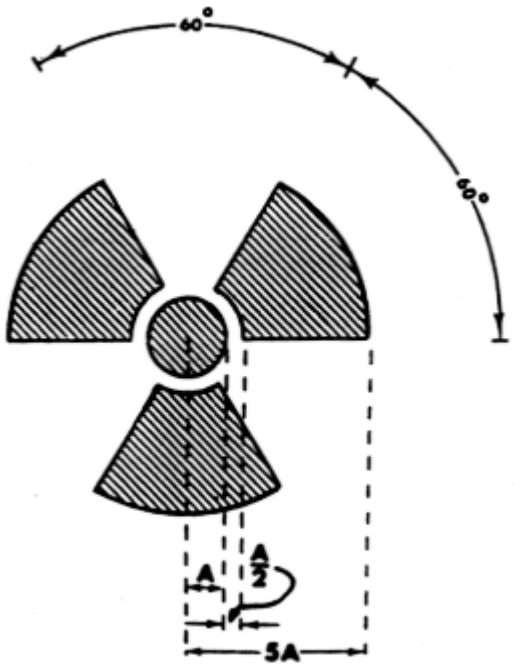
12VAC5-481-850. Radiation Symbol; Caution Signs.

Article 10. Precautionary Procedures

A. Unless otherwise authorized by the agency, the symbol prescribed by this section shall use the colors magenta, purple, or black on a yellow background. The symbol prescribed by this section is the three-bladed design:

1. The cross-hatched area is to be magenta, purple, or black, and

2. The background is to be yellow.



RADIATION SYMBOL

B. Exception to color requirements for standard radiation symbol.Notwithstanding the requirements of subsection A of this section, licensees are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures with conspicuously etched or stamped radiation caution symbols and without a color requirement.

C. Additional information on signs and labels. In addition to the contents of signs and labels prescribed in this section, the licensee may provide on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

12VAC5-481-860. Posting Requirements.

A. Licensees shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol as described in 12VAC5-481-850 and the words "CAUTION, RADIATION AREA."

B. Licensees shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol as described in 12VAC5-481-850 and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

C. Licensees shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol as described in 12VAC5-481-850 and the words "GRAVE DANGER, VERY HIGH RADIATION AREA."

D. Licensees shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol as described in 12VAC5-481-850 and the words, "CAUTION, AIRBORNE RADIOACTIVITY AREA," or "DANGER, AIRBORNE RADIOACTIVITY AREA."

E. The licensee shall post each area or room in which there is used or stored an amount of

licensed material exceeding 10 times the quantity of such material specified in 12VAC5-481-3700 with a conspicuous sign or signs bearing the radiation symbol as described in 12VAC5-481-850 and the words "CAUTION, RADIOACTIVE MATERIALS" or "DANGER, RADIOACTIVE MATERIALS."

12VAC5-481-870. Exceptions to Posting Requirements.

A. Licensees are not required to post caution signs in areas or rooms containing radioactive materials for periods of less than eight hours, if the following conditions are met:

1. The materials are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to radiation or radioactive materials in excess of the limits established in this part; and

2. The area or room is subject to the licensee's control.

B. Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to 12VAC5-481-860 , provided that the patient could be released from licensee control pursuant to 12VAC5-481-1870 .

C. A room or area is not required to be posted with a caution sign because of the presence of a sealed source, provided that the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 5 millirem (0.05 mSv) per hour.

D. Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under 12VAC5-481-860 if

1. Access to the room is controlled pursuant to 12VAC5-481-2043; and

2. Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in this part.

12VAC5-481-880. Labeling Containers and Radiation Machines.

A. Licensees shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol as described in 12VAC5-481-850 and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall also provide sufficient information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers or working in the vicinity of the containers to take precautions to avoid or minimize exposures.

B. Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner that cautions individuals that radiation is produced when it is energized.

C. Licensees shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

12VAC5-481-890. Exemptions to Labeling Requirements.

Licensees are not required to label:

1. Containers holding licensed material in quantities less than the quantities listed in 12VAC5-481-3700;

2. Containers holding licensed material in concentrations less than those specified in Appendix B to 10 CFR Part 20;

3. Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this part;

4. Containers when they are in transport and packaged and labeled in accordance with regulations of the U.S. Department of Transportation;

5. Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by readily available written record (e.g., containers in locations such as water filled canals, storage vaults, or hot cells). The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

6. Installed manufacturing or process equipment, such as reactor components, piping, and tanks.

12VAC5-481-900. Procedures for Receiving and Opening Packages.

A. Licensees who expect to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in 12VAC5-481-10 and 12VAC5-481-3770 , shall make arrangements to receive:

1. The package when the carrier offers it for delivery; or

2. Notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

B. Licensees shall monitor the following:

1.The external surfaces of a labeled package for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as defined in 12VAC5-481-10 ;

2. The external surfaces of a labeled package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 12VAC5-481-10 and 12VAC5-481-3770; and

3. All packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

C. Licensees shall perform the monitoring required by subsection B of this section as soon as

practical after receipt of the package, but not later than three hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, if there is evidence of degradation of package integrity (e.g., packages that are crushed, wet, or damaged), or if it is received after working hours, not later than three hours from the beginning of the next working day.

D. Licensees shall immediately notify the final delivery carrier and the agency by telephone, when:

1. Removable contamination exceeds the limits of subdivision 9 of 12VAC5-481-3080; or

2. External radiation levels exceed the limits of subdivision 10 of 12VAC5-481-3080 .

E. Licensees shall:

1. Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

2. Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

F. Licensees transferring special form sources in licensee-owned or licensee-operated vehicles to and from a work site are exempt from the contamination monitoring requirements of subsection B of this section, but are not exempt from the survey requirements in subsection B of this section for measuring radiation levels that are required to ensure that the source is still properly lodged in its shield.

12VAC5-481-910. General Requirements.

Article 11. Waste Disposal

A. Licensees shall dispose of licensed material only in the following ways:

1. By transfer to an authorized recipient as provided in 12VAC5-481-570;

2. By decay in storage;

3. By release in effluents within the limits of 12VAC5-481-720; or

4. As authorized under 12VAC5-481-920 , 12VAC5-481-930 , 12VAC5-481-940 , 12VAC5-481-950 , or 12VAC5-481-971 .

B. A person shall be specifically licensed to receive waste containing licensed material from other persons for the following actions:

1. Treatment prior to disposal;

2. Treatment or disposal by incineration;

3. Decay in storage;

4. Disposal at a land disposal facility licensed under Part XI (12VAC5-481-2330 et seq.) of this chapter; or

5. Disposal at a geologic repository under 10 CFR Part 60 or 10 CFR Part 63.

12VAC5-481-920. Method for Obtaining Approval of Proposed Disposal Procedures.

A licensee or registrant or applicant for a license or registration may apply to the agency for approval of proposed procedures, not otherwise authorized in these regulations, to dispose of licensed or registered material generated in the licensee's or registrant's operations. Each application shall include:

1. A description of the waste containing licensed or registered material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal;

2. An analysis and evaluation of pertinent information on the nature of the environment;

3. The nature and location of other potentially affected facilities; and

4. Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in Part IV (12VAC5-481-600 et seq.) of this chapter.

12VAC5-481-930. Disposal by Release into Sanitary Sewerage.

A. Licensees may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

1. The licensed or other radioactive material is readily soluble or is readily dispersible biological material in water;

2. The quantity of licensed or other radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in Table 3 of Appendix B to 10 CFR Part 20;

3. If more than one radionuclide is released, the following conditions shall also be satisfied:

a. The licensee shall determine the fraction of the limit in Table 3 of Appendix B to 10 CFR Part 20 represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in Table 3 of Appendix B to 10 CFR Part 20; and

b. The sum of the fractions for each radionuclide required by subdivision 3 a of this subsection does not exceed unity; and

4. The total quantity of licensed and other radioactive material that the licensee releases into the sanitary sewerage system in one year does not exceed 5 curies (185 GBq) of hydrogen-3, 1 curie (37 GBq) of carbon-14, and 1 curie (37 GBq) of all other radioactive materials combined.

B. Excreta from individuals undergoing medical diagnosis or therapy with radioactive

material are not subject to the limitations contained in this section.

12VAC5-481-940. Treatment or Disposal by Incineration.

Licensees may treat or dispose of licensed material by incineration only if the material is in a form or concentration specified in 12VAC5-481-950 , or as specifically approved by the agency pursuant to 12VAC5-481-920 .

12VAC5-481-950. Disposal of Specific Wastes.

A. Licensees may dispose of the following licensed material as if it were not radioactive:

1. 0.05 µCi (1.85 kBq) or less of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

2. 0.05 µCi (1.85 kBq) or less of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

B. Licensees may not dispose of tissue under subdivision A 2 of this section in a manner that would permit its use either as food for humans or as animal feed.

C. Licensees shall maintain records in accordance with 12VAC5-481-1060 .

12VAC5-481-960. Transfer for Disposal and Manifests.

A. The requirements of this section and 12VAC5-481-3710 are designed to accomplish the following:

1. Control transfers of low level radioactive waste by any waste generator, waste collector, or waste processor licensee that ships low level waste either directly or indirectly through a waste collector or waste processor to a licensed low level waste land disposal facility (as defined in 12VAC5-481-10);

2. Establish a manifest tracking system; and

3. Supplement existing requirements concerning transfers and recordkeeping for those wastes.

B. Licensees shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility shall document the information required and transfer this recorded information to the intended consignee in accordance with 12VAC5-481-3710 .

C. Each shipment manifest shall include a certification by the waste generator as specified in 12VAC5-481-3710 G.

D. Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in 12VAC5-481-3710 H.

E. Licensees shipping radioactive material as defined in subdivisions 3 and 4 under the definition of "byproduct material" in 12VAC5-481-10 intended for ultimate disposal at a land

disposal facility licensed under Part XI (12VAC5-481-2330 et seq.) of this chapter, 10 CFR Part 61, or equivalent agreement state regulations shall document the information required on a manifest and transfer this recorded manifest information to the intended consignee in accordance with 12VAC5-481-3710 .

12VAC5-481-970. Compliance with Environmental and Health Protection Regulations.

Nothing in this part relieves the licensee from complying with other applicable federal, state, and local regulations governing any other toxic or hazardous properties of materials that may be disposed of under this part.

12VAC5-481-971. Disposal of Certain Radioactive Material.

A. Licensed material meeting the definition in subdivisions 3 and 4 of the definition of "byproduct material" in 12VAC5-481-10 may be disposed of in accordance with Part XI (12VAC5-481-2330 et seq.) of this chapter, even though it is not defined as low level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility or transferred for ultimate disposal at a facility licensed under Part XI (12VAC5-481-2330 et seq.) of this chapter, 10 CFR Part 61, or equivalent agreement state regulations shall meet the requirements of 12VAC5-481-960 .

B. A licensee may dispose of byproduct material, as defined in subsection A of this section, at a disposal facility authorized to dispose of such material in accordance with any federal or state solid or hazardous waste law, including the Solid Waste Disposal Act (42 USC § 6901 et seq.).

12VAC5-481-980. General Provisions.

Article 12. Records

A. Licensees shall (i) use the units curie, rad, rem, and roentgen, including multiples and subdivisions, and may include the International System of Units (SI) units (Becquerel, gray, sievert, and coulomb per kilogram) and (ii) clearly indicate the units of all quantities on records required by this part.

B. Notwithstanding the requirements of subsection A of this section, when recording information on shipment manifests as required in 12VAC5-481-960 B, information shall be recorded in SI units or in SI units and units as specified in subsection A of this section.

C. The licensee shall make a clear distinction among the quantities entered on the records required by this part (e.g., total effective dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, and committed dose equivalent).

12VAC5-481-990. Records of Radiation Protection Programs.

A. Licensees shall maintain records of the radiation protection program, including:

1. The provisions of the program; and

2. Audits and other reviews of program content and implementation.

B. Licensees shall retain the records required by subdivision A 1 of this section until the agency terminates each pertinent license requiring the record. Licensees shall retain the records required by subdivision A 2 of this section for three years after the record is made.

12VAC5-481-1000. Records of Surveys.

A. Licensees shall maintain records showing the results of surveys and calibrations required by 12VAC5-481-750 and 12VAC5-481-900 B. Licensees shall retain these records for three years after the record is made.

B. Licensees shall retain each of the following records until the agency terminates each pertinent license condition requiring the record:

1. Records of the results of surveys to determine the dose from external sources and used in the absence of or in combination with individual monitoring data in the assessment of individual dose equivalents;

2. Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose;

3. Records showing the results of air sampling, surveys, and bioassays required pursuant to 12VAC5-481-830 A 3; and

4. Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

12VAC5-481-1010. Records of Tests for Leakage or Contamination of Sealed Sources.

Records of tests for leakage or contamination of sealed sources (required by 12VAC5-481-740) shall be kept in units of becquerel or microcurie and maintained for five years after the records are made.

12VAC5-481-1020. Records of Prior Occupational Dose.

The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in 12VAC5-481-680 on an occupational radiation exposure form provided by the agency or equivalent until the agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing an occupational radiation exposure form provided by the agency or equivalent for three years after the record is made.

12VAC5-481-1030. Records of Planned Special Exposures.

A. For each use of the provisions of 12VAC5-481-690 for planned special exposures, licensees shall maintain records that describe the following:

1. The exceptional circumstances requiring the use of a planned special exposure;

2. The name of the management official who authorized the planned special exposure and a copy of the signed authorization;

3. What actions were necessary;

4. Why the actions were necessary;

5. How doses were maintained ALARA; and

6. What individual and collective doses results were expected and the doses actually received in the planned special exposure.

B. Licensees shall retain the records until the agency terminates each pertinent license requiring these records.

12VAC5-481-1040. Records of Individual Monitoring Results.

A. Licensees shall maintain records of doses received by all individuals for whom monitoring is required pursuant to 12VAC5-481-760 and records of doses received during planned special exposures, accidents, and emergency conditions. These records shall include, when applicable:

1. The deep dose equivalent to the whole body, lens deep dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities;

2. The estimated intake of radionuclides (see 12VAC5-481-650);

3. The committed effective dose equivalent assigned to the intake of radionuclides;

4. The specific information used to assess the committed effective dose equivalent pursuant to 12VAC5-481-670 A and C and when required by 12VAC5-481-760 ;

5. The total effective dose equivalent when required by 12VAC5-481-650; and

6. The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

B. Licensees shall make entries of the records specified in subsection A of this section at least annually.

C. Licensees shall maintain the records specified in subsection A of this section in clear and legible records containing all the information required by 12VAC5-481-2280 .

D. The records required under this section should be protected from public disclosure because of the personal privacy nature of the records. These records are protected by privacy laws, including when the records are transferred to the agency.

E. Licensees shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

F. Licensees shall retain the required form or record until the agency terminates each pertinent license requiring this record.

12VAC5-481-1050. Records of Dose to Individual Members of the Public.

A. Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public per 12VAC5-481-720 .

B. The licensee or registrant shall retain the records required by subsection A of this section until the agency terminates each pertinent license or registration requiring the record.

12VAC5-481-1060. Records of Waste Disposal.

A. Each licensee or registrant shall maintain records of the disposal of licensed or registered materials made pursuant to 12VAC5-481-920 through 12VAC5-481-950 , Part XI (12VAC5-481-2330 et seq.) of this chapter, and disposal by burial in soil, including burials authorized before, September 1, 1980, of the rule that removed the authorization.

B. The licensee or registrant shall retain the records required by subsection A of this section until the agency terminates each pertinent license or registration requiring the record.

12VAC5-481-1070. Records of Testing Entry Control Devices for Very High Radiation Areas.

A. Each licensee or registrant shall maintain records of tests made on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

B. The licensee or registrant shall retain the records required by subsection A of this section for three years after the record is made.

12VAC5-481-1080. Form of Records.

Each record required by Part IV (12VAC5-481-600 et seq.) of this chapter shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

12VAC5-481-1090. Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.

Article 13. Reports

A. Each licensee or registrant shall report to the agency by telephone as follows:

1. Immediately after its occurrence becomes known to the licensee, stolen, lost, or missing licensed or registered radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in 12VAC5-481-3700;

2. Within 30 days after its occurrence becomes known to the licensee, lost, stolen, or missing licensed or registered radioactive material in an aggregate quantity greater than 10 times the quantity specified in 12VAC5-481-3700 that is still missing; or

3. Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

B. Each licensee or registrant required to make a report pursuant to subsection A of this section shall, within 30 days after making the telephone report, make a written report to the agency setting forth the following information:

1. A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;

2. A description of the circumstances under which the loss or theft occurred;

3. A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved;

4. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;

5. Actions that have been taken, or will be taken, to recover the source of radiation; and

6. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

C. Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.

D. The licensee or registrant shall prepare any report filed with the agency pursuant to this section so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

12VAC5-481-1100. Notification of Incidents.

A. Notwithstanding any other requirements for notification, licensees shall immediately report each event involving radioactive material possessed by the licensee that may have caused or threatens to cause any of the following conditions:

1. An individual to receive:

a. A total effective dose equivalent of 25 rem (0.25 Sv) or more;

b. A lens dose equivalent of 75 rem (0.75 Sv) or more; or

c. A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 250 rad (2.5 Gy) or more; and

2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational annual limits on intake. The provision of this subdivision does not apply to locations where personnel are not normally stationed during routine operations, such as hot cells or process enclosures.

B. Licensees shall, within 24 hours of discovery of the event, report any event involving loss of control of a licensed material possessed by the licensee that may have caused, or threatened to cause, any of the following conditions:

1. An individual to receive, in a period of 24 hours:

a. A total effective dose equivalent exceeding 5 rem (0.05 Sv);

b. A lens dose equivalent exceeding 15 rem (0.15 Sv); or

c. A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 50 rem (0.5 Sv); and

2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational annual limits on intake. The provisions of this subdivision do not apply to locations where personnel are not normally stationed during routine operations, such as hot cells or process enclosures.

C. Licensees shall prepare any report filed with the agency pursuant to this section so that names of individuals who received exposure to radiation or radioactive material are stated in a separate and detachable part of the report.

D. Reports made by licensees in response to the requirements of this section shall be made, via telephone, to the agency at (804) 864-8150 during normal business hours and to the State Emergency Operations Center at (804) 674-1110 after normal business hours.

E. The provisions of this section do not include doses that result from planned special exposures, provided that such doses are within the limits for planned special exposures, and are reported under 12VAC5-481-1120 .

12VAC5-481-1110. Reporting Requirements.

A. Licensees shall notify the agency as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.). Licensees shall:

1. If required by this subsection and subsection B, notify the agency of any event, via

telephone, during normal business hours to (804) 864-8150 or after hours to the State Emergency Operations Center at (804) 624-2400.

2. Submit a written report, either by mail or by hand delivery to the agency at 109 Governor Street, 7th Floor, Richmond, VA 23219.

B. Licensees shall notify the agency within 24 hours after the discovery of any of the following events involving licensed material:

1. An unplanned contamination event that:

a. Requires access to the contaminated area by workers or the public to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

b. Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B to 10 CFR Part 20; and

c. Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

2. An event in which equipment is disabled or fails to function as designed when:

a. The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

b. The equipment is required to be available and operable when it is disabled or fails to function; and

c. No redundant equipment is available and operable to perform the required safety function.

3. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

4. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

a. The quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B to 10 CFR Part 20; and

b. The damage affects the integrity of the licensed material or its container.

C. Notifications of any event made by licensees in response to the requirements of subsections A and B of this section shall be made to the agency, via telephone, during normal business hours to (804) 864-8150 or after hours to the State Emergency Operations Center at (804) 624-2400 and provide the following:

1. To the extent that the information is available at the time of the notification, provide a name and call back telephone number;

2. A description of the event, including date and time; if known, the sequence of occurrences leading to the event including degradation or failure of structures, systems, equipment, components; and activities of personnel relied on to prevent potential accidents;

3. The exact location of the event and whether the remaining structures, systems, equipment, components, and activities of personnel relied on to mitigate the consequences are available and reliable to perform their function;

4. Radiological or chemical hazards involved including the isotopes, quantities, and chemical and physical form of the licensed material;

5. Actual or potential health and safety consequences to the workers, the public, and the environment, including relevant chemical and any radiation data for actual personnel exposures to radiation or radioactive materials or hazardous chemicals produced from licensed material;

6. External conditions affecting the event;

7. Status of the event including actions taken by the licensee in response to the event and the current and planned site status;

8. Notification, related to the event, that were made or are planned to be made to any other local, state, or federal agencies; and

9. Status of any press releases related to the event that were made or are planned.

D. In addition to the notifications required by 12VAC5-481-1100 or subsections A and B of this section, each licensee shall submit a written report within 30 days after learning of any of the following occurrences, either by mail or by hand delivery, to the agency at 109 Governor Street, 7th Floor, Richmond, VA 23219:

1. Any incident for which notification is required by 12VAC5-481-1100 or subsections A and B of this section;

2. Doses in excess of any of the following:

a. The occupational dose limits for adults in 12VAC5-481-640;

b. The occupational dose limits for a minor in 12VAC5-481-700;

c. The limits for an embryo/fetus of a declared pregnant woman in 12VAC5-481-710;

d. The limits for an individual member of the public in 12VAC5-481-720;

e. Any applicable limits in the license; or

f. The ALARA constraints for air emissions established under 12VAC5-481-630 D;

3. Levels of radiation or concentrations of radioactive material in:

a. A restricted area in excess of any applicable limit in the license; or

b. An unrestricted area in excess of 10 times any applicable limit set forth in this part or in the license, whether or not involving exposure of any individual in excess of the limits in 12VAC5-481-720; or

4. For licensee subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR Part 190, levels of radiation or releases of radioactive materials in excess of those standards, or of license conditions related to those standards.

E. Each report, required by subsection A of this section shall:

1. Describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

a. A description of the event, including the probable cause, the exact location, the isotopes and quantities, chemical and physical form of the licensed material involved, date and time of the event, and if applicable, the manufacturer and model number of any equipment that failed or malfunctioned;

b. Estimates of each individual's dose;

c. The levels of radiation and concentrations of radioactive material involved;

d. The cause of the elevated exposures, dose rates, or concentrations; and

e. Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license conditions and the results of all evaluations or assessments.

2. Include for each individual the name, social security number, and date of birth. With respect to the limit for the embryo/fetus, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable part of the report and shall be clearly labeled for protection under privacy laws.

12VAC5-481-1120. Reports of Planned Special Exposures.

The licensee or registrant shall submit a written report to the agency within 30 days following any planned special exposure conducted in accordance with 12VAC5-481-690 , informing the agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by 12VAC5-481-1030 .

12VAC5-481-1130. Reports of Individual Monitoring.

A. This section applies to each person licensed or registered by the agency to:

1. Possess or use sources of radiation for purposes of industrial radiography pursuant to Parts III (12VAC5-481-380 et seq.) and V (12VAC5-481-1170 et seq.) of this chapter; or

2. Receive radioactive waste from other persons for disposal pursuant to Part XI (12VAC5-

481-2330 et seq.) of this chapter; or

3. Possess or use at any time, for processing or manufacturing for distribution pursuant to Part III (12VAC5-481-380 et seq.) or VII (12VAC5-481-1660 et seq.) of this chapter, radioactive material in quantities exceeding any one of the following quantities:

Radionuclide	Activity[a] GBq	Ci
Cesium-137	37	1
Cobalt-60	37	1
Gold-98	3,700	100
Iodine-131	37	1
Iridium-192	270	10
Krypton-85	37,000	1,000
Promethium-147	370	10
Technecium-99m	37,000	1,000

[a]The agency may require as a license condition,or by rule, regulation, or an order pursuant to 12VAC5-481-190 , reports fromlicensees or registrants who are licensed or registered to use radionuclidesnot on this list, in quantities sufficient to cause comparable radiationlevels.

B. Each licensee or registrant in a category listed in subsection A of this section shall submit an annual report of the results of individual monitoring carried out by the licensee or registrant for each individual for whom monitoring was required by 12VAC5-481-760 during that year. The licensee or registrant may include additional data for individuals for whom monitoring was provided but not required. The licensee or registrant shall use the agency's record of individual monitoring results form or equivalent or electronic media containing all the information required by the agency's record of individual monitoring results form.

C. The licensee or registrant shall file the report required by subsection B of this section, covering the preceding year, on or before April 30 of each year. The licensee or registrant shall submit the report to the agency.

12VAC5-481-1140. Notifications and Reports to Individuals.

A. Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in 12VAC5-481-2280 .

B. When a licensee or registrant is required pursuant to 12VAC5-481-1110 to report to the agency any exposure of an individual to radiation or radioactive material, the licensee or

registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the agency, and shall comply with the provisions of 12VAC5-481-2280 A.

12VAC5-481-1150. Reports of Leaking or Contaminated Sealed Sources.

The licensee or registrant shall file a report within five days with the agency if the test for leakage or contamination required pursuant to 12VAC5-481-740 indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results and the corrective action taken.

12VAC5-481-1151. Reports of Transactions Involving Nationally Tracked Sources.

A. Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;

3. The manufacturer, model, and serial number of the source;

4. The radioactive material in the source;

5. The initial source strength in becquerels (curies) at the time of manufacture; and

6. The manufacture date of the source.

B. Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;

3. The name and license number of the recipient facility and the shipping address;

4. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

5. The radioactive material in the source;

6. The initial or current source strength in becquerels (curies);

7. The date for which the source strength is reported;

8. The shipping date;

9. The estimated arrival date; and

10. For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.

C. Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;

3. The name, address, and license number of the person that provided the source;

4. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

5. The radioactive material in the source;

6. The initial or current source strength in becquerels (curies);

7. The date for which the source strength is reported;

8. The date of receipt; and

9. For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

D. Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;

3. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

4. The radioactive material in the source;

5. The initial or current source strength in becquerels (curies);

6. The date for which the source strength is reported; and

7. The disassemble date of the source.

E. Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;

3. The waste manifest number;

4. The container identification with the nationally tracked source;

5. The date of disposal; and

6. The method of disposal.

F. The reports discussed in subsections A through E of this section must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

1. The online National Source Tracking System;

2. Electronically using a computer-readable format;

3. By facsimile;

4. By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

5. By telephone with followup by facsimile or mail.

G. Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within five business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by subsections A through E of this section. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

12VAC5-481-1160. (Repealed.)

Article 14. Additional Requirements

12VAC5-481-1161. Radiological Criteria for License Termination.

A. General provisions and applicability.

1. This part applies to the decommissioning of facilities licensed under this chapter.

2. This part does not apply to sites that:

a. Have been decommissioned before the effective date as stated in 12VAC5-481-160; or

b. Have previously submitted and received NRC's approval on a license termination plan or decommissioning plan.

3. After a site has been decommissioned and the license terminated according to this section, the agency shall require additional cleanup only if, based on new information, the agency determines that the criteria of this part were not met and residual radioactivity remaining at the site could result in a significant threat to public health and safety.

4. When calculating the Total Effective Dose Equivalent (TEDE) to the average member of the critical group, the licensee shall determine the peak annual TEDE expected within the first 1,000 years after decommissioning.

B. Radiological criteria for unrestricted use. A site is considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 0.25 mSv (25 mrem) per year, including that from groundwater sources of drinking water; and the residual radioactivity has been reduced to levels that are ALARA. Determination of levels that are ALARA shall take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

C. Criteria for termination under restricted conditions. A site is considered acceptable for license termination under restricted conditions, if the licensee:

1. Can demonstrate that further reductions in residual radioactivity necessary to comply with subsection B of this section would result in net public or environmental harm or are not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels that are ALARA shall take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal;

2. Has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity, distinguishable from background radiation, will not exceed 0.25 mSv (25 mrem) per year to the average member of the critical group;

3. Has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

a. Funds placed into an account segregated from the licensee's assets and outside the licensee's administrative control as described under 12VAC5-481-450 C 7 a;

b. Surety method, insurance, or other guarantee method as described under part 12VAC5-481-450 C 7 b;

c. A statement of intent, in the case of federal, state, or local government licensees, as described in 12VAC5-481-450 C 7 d; or

d. When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by the governmental entity;

4. Has submitted a decommissioning plan or a license termination plan to the agency indicating the licensee's intent to decommission according to 12VAC5-481-510 and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the license termination plan or decommissioning plan how the advice of individuals and institutions in the community has been sought according to subdivisions 5 and 6 of this subsection and incorporated, as appropriate, following analysis of that advice;

5. If proposing to decommission by restricting use of the site, seeks advice from individuals and institutions in the community who may be affected by the decommissioning regarding whether:

a. Institutional controls proposed by the licensee:

(1) Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background radiation to the average member of the critical group will not exceed 0.25 mSv (25 mrem) TEDE per year;

(2) Will be enforceable; and

(3) Will not impose undue burdens on the local community or other affected parties; and

b. The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site;

6. While seeking advice under subdivision 5 of this subsection, provides for:

a. Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

b. An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

c. A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

7. Reduces residual radioactivity at the site so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background radiation to the average member of the critical group is ALARA and would not exceed:

a. 1 mSv (100 mrem) per year; or

b. 5 mSv (500 mrem) per year, if the licensee:

(1) Demonstrates that further reductions in residual radioactivity necessary to comply with subdivision C 7 a of this section are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(2) Makes provisions for durable institutional controls; and

(3) Provides sufficient financial assurance, according to subdivision C 3 of this section, to enable a responsible governmental entity or independent third party, including a governmental custodian of a site, to carry out periodic rechecks of the site no less frequently than every five years to ensure that the institutional controls remain in place as necessary to meet the criteria of subdivision C 2 of this section, and to assume and carry out responsibilities for any necessary control and maintenance of those controls.

D. Alternative criteria for license termination.

1. The agency may terminate a license using alternative criteria greater than the dose criterion of subsection B and subdivision C 5 a (1) of this section, if the licensee:

a. Provides assurance that public health and safety would continue to be protected and that it is unlikely that the dose from all manmade sources combined, other than medical, would be more than the 1 mSv (100 mrem) per year limit under 12VAC5-481-720 , by submitting an analysis of possible sources of exposure;

b. Employs, to the extent practical, restrictions on site use according to subsection C of this section, in minimizing exposures at the site;

c. Reduces doses to ALARA levels, taking into consideration any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal; and

d. Submits a decommissioning plan or license termination plan to the agency indicating the licensee's intent to decommission according to 12VAC5-481-510 , and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or license termination plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

(1) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(2) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(3) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.

2. Has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

3. The use of alternate criteria to terminate a license requires the approval of the agency after consideration of staff recommendations of the agency that address any comments

provided by federal, state, and local governments and any public comments submitted pursuant under subsection E of this section.

E. Public notification and public participation. Upon receipt of a license termination plan or decommissioning plan from a licensee or a proposal by a licensee for release of a site according to subsection C or D of this section, or whenever the agency deems such notice to be in the public interest, the agency shall:

1. Notify and solicit comments from:

a. Local and state governments in the vicinity of the site and any Indian Nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and

b. The U.S. Environmental Protection Agency and Virginia Department of Environmental Quality for cases when the licensee proposes to release a site according to subsection D of this section; and

2. Publish a notice in the Virginia Register of Regulations and in a forum, such as local newspapers, letters to state and local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site and solicit comments from affected parties.

12VAC5-481-1170. Purpose.

Part V. Radiation Safety Requirements For Industrial Radiographic Operations

Article 1. General Requirements

This part prescribes requirements for the issuance of licenses or registrations for the industrial use of sources of radiation and radiation safety requirements for persons using these sources of radiation in industrial radiography.

12VAC5-481-1180. Scope.

The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of these regulations. In particular, the general requirements and provisions of Parts I (12VAC5-481-10 et seq.); II (12VAC5-481-260 et seq.); III (12VAC5-481-380 et seq.); IV (12VAC5-481-600 et seq.); X (12VAC5-481-2250 et seq.) and XIII (12VAC5-481-2950 et seq.), of this chapter apply to applicants, licensees and registrants subject to this part. Parts III (12VAC5-481-380 et seq.) and XIII (12VAC5-481-2950 et seq.) of this chapter apply to licensing and transportation of radioactive material and Part II (12VAC5-481-260 et seq.) of this chapter applies to the registration of radiation machines. Except for sections that are applicable only to sealed radioactive sources, radiation machines and sealed radioactive sources are both covered by this part. This regulation does not apply to medical uses of sources of radiation that are addressed in Parts VII (12VAC5-481-1660 et seq.) and XV (12VAC5-481-3380 et seq.) of this chapter.

12VAC5-481-1190. Exemptions.

A. Uses of certified and certifiable cabinet X-ray systems are exempt from the requirements of this part except for 12VAC5-481-1200 and the following:

1. For certified and certifiable cabinet X-ray systems, including those designed to allow admittance of individuals:

a. No registrant shall permit any individual to operate a cabinet X-ray system until the individual has received a copy of and instruction in the operating procedures for the unit. Records that demonstrate compliance with this subdivision shall be maintained for agency inspection until disposal is authorized by the agency.

b. Tests for proper operation of interlocks must be conducted and recorded at intervals not to exceed six months. Records of these tests shall be maintained for agency inspection until disposal is authorized by the agency.

c. The registrant shall perform an evaluation of the radiation dose limits to determine compliance with 12VAC5-481-720 and 21 CFR 1020.40, Cabinet X-ray Systems, at intervals not to exceed one year. Records of these evaluations shall be maintained for agency inspection for two years after the evaluation.

2. Certified cabinet X-ray systems shall be maintained in compliance with 21 CFR 1020.40, Cabinet X-ray Systems, and no modification shall be made to the system unless prior agency approval has been granted.

B. Industrial uses of hand-held light intensified imaging devices are exempt from the requirements of exceed 0.2 mSv (2 mrem) per hour. Devices that exceed this limit shall meet the applicable requirements of this part and the licensing or registration requirements of Part II (12VAC5-481-260 et seq.) or Part III (12VAC5-481-380 et seq.) of this chapter, as applicable.

12VAC5-481-1200. Licensing and Registration Requirements for Industrial Radiography Operations.

A. The agency will approve an application for a specific license for the use of licensed material or a registration for use of radiation machines if the applicant meets the following requirements:

1. The applicant satisfies the general requirements specified in Part II (12VAC5-481-260 et seq.) for radiation machine facilities or Part III (12VAC5-481-380 et seq.) for radioactive material, as applicable, and any special requirements contained in this part;

2. The applicant submits an adequate program for training radiographers and radiographer's assistants that meets the requirements of 12VAC5-481-1320;

3. The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid;

4. The applicant submits written operating and emergency procedures as described in

12VAC5-481-1330;

5. The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer's assistant at intervals not to exceed six months as described in 12VAC5-481-1320 E;

6. The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility;

7. The applicant submits the qualifications of the individual(s) designated as the radiation safety officer as described in 12VAC5-481-1310 A 1;

8. If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing the test. The description must include the:

a. Methods of collecting the samples;

b. Qualifications of the individual who analyzes the samples;

c. Instruments to be used; and

d. Methods of analyzing the samples;

9. If the applicant intends to perform calibrations of survey instruments and alarming ratemeters, the applicant must describe methods to be used and the experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in 12VAC5-481-1240 and 12VAC5-481-1350 G 4;

10. The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations;

11. The applicant identifies the location(s) where all records required by this and other parts of these regulations will be maintained;

12. If a license application includes underwater radiography, a description of:

a. Radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;

b. Radiographic equipment and radiation safety equipment unique to underwater radiography; and

c. Methods for gas-tight encapsulation of equipment; and

13. If an application includes offshore platform and/or lay-barge radiography, a description of:

a. Transport procedures for radioactive material to be used in industrial radiographic operations;

b. Storage facilities for radioactive material; and

c. Methods for restricting access to radiation areas.

B. A license or registration will be issued if the requirements of subsection A of this section, as applicable, are met.

12VAC5-481-1210. Performance Requirements for Industrial Radiography Equipment.

A. Equipment used in industrial radiographic operations must meet the following minimum criteria:

Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standard Institute, N4321980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981). This publication may be purchased from the American National Standards Institute, Inc., 25 West 43rd Street, New York, NY 10036; telephone (212) 6424900.

B. In addition to the requirements specified in this section the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources:

1. The licensee shall ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the:

a. Chemical symbol and mass number of the radionuclide in the device;

b. Activity and the date on which this activity was last measured;

c. Model or product code and serial number of the sealed source;

d. Name of the manufacturer of the sealed source; and

e. Licensee's name, address, and telephone number.

2. Radiographic exposure devices intended for use as Type B packages must meet the applicable transportation requirements of Part XIII (12VAC5-481-2950 et seq.) of this chapter.

3. Modification of radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless approved by the agency or other approval body.

C. In addition to the requirements specified in subsections A and B of this section, the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operations or to source changers:

1. The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside

the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

2. The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

3. The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers that must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

4. Each sealed source or source assembly must have attached to it or engraved on it, a durable, legible, visible label with the words:

"DANGER—RADIOACTIVE."

The label may not interfere with the safe operation of the exposure device or associated equipment.

5. The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.

6. Guide tubes must be used when moving the source out of the device.

7. An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during industrial radiography operations.

8. The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N4321980.

9. Source changers must provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

D. All radiographic exposure devices and associated equipment in use after January 10, 1996, must comply with the requirements of this section.

E. As an exception to subsection A of this section, equipment used in industrial radiographic operations need not comply with 8.9.2(c) of the Endurance Test in American National Standards Institute N4321980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can reasonably exert on the lever or crankshaft of the drive mechanism.

12VAC5-481-1220. Limits on External Radiation Levels from Storage Containers and Source Changers.

The maximum exposure rate limits for storage containers and source changers are 2 mSv (200 mrem) per hour at any exterior surface, and 0.1 mSv (10 mrem) per hour at one meter from any exterior surface with the sealed source in the shielded position.

12VAC5-481-1230. Locking of Sources of Radiation, Storage Containers and Source Changers.

A. Each radiographic exposure device must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device and/or its container must be kept locked, and if a keyed-lock, with the key removed at all times, when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in 12VAC5-481-1370 . In addition, during radiographic operations the sealed source assembly must be secured in the shielded position each time the source is returned to that position.

B. Each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be kept locked, and if a keyed-lock, with the key removed at all times, when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

C. The control panel of each radiation machine shall be equipped with a lock that will prevent the unauthorized use of an X-ray system or the accidental production of radiation. The radiation machine shall be kept locked and the key removed at all times except when under the direct visual surveillance of a radiographer or a radiographer's assistant.

12VAC5-481-1240. Radiation Survey Instruments.

A. The licensee or registrant shall keep sufficient calibrated and operable radiation survey instruments at each location where sources of radiation are present to make the radiation surveys required by this part and by Part IV (12VAC5-481-600 et seq.) of this chapter. Instrumentation required by this section must be capable of measuring a range from 0.02 mSv (2 mrem) per hour through 0.01 Sv (1 rem) per hour.

B. The licensee or registrant shall have each radiation survey instrument required under subsection A of this section calibrated:

1. At energies appropriate for use and at intervals not to exceed six months or after instrument servicing, except for battery changes;

2. For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at three points between 0.02 and 10 mSv (2 and 1000 mrem) per hour; and

3. So that an accuracy within plus or minus 20% of the true radiation dose rate can be demonstrated at each point checked.

C. The licensee or registrant shall maintain records of the results of the instrument

calibrations in accordance with 12VAC5-481-1410 .

12VAC5-481-1250. Leak Testing and Replacement of Sealed Sources.

A. The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source must be performed by persons authorized to do so by the agency, the NRC, or another agreement state.

B. The opening, repair, or modification of any sealed source must be performed by persons specifically authorized to do so by the agency, the NRC, or another agreement state.

C. Testing and recordkeeping requirements.

1. Each licensee who uses a sealed source shall have the source tested for leakage at intervals not to exceed six months. The leak testing of the source must be performed using a method approved by the agency, the NRC, or by another agreement state. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 185 Bq (0.005 µCi) of radioactive material on the test sample and must be performed by a person specifically authorized by the agency, the NRC, or another agreement state to perform the analysis.

2. The licensee shall maintain records of the leak tests in accordance with 12VAC5-481-1420 .

3. Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within six months before the transfer, it may not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the interval of storage exceeds six months.

D. Any test conducted pursuant to subsections B and C of this section that reveals the presence of 185 Bq (0.005 µCi) or more of removable radioactive material must be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall have it decontaminated and repaired or disposed of in accordance with agency regulations. A report must be filed with the agency within five days of any test with results that exceed the threshold in this paragraph, describing the equipment involved, the test results, and the corrective action taken.

E. Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of 185 Bq (0.005 µCi) of radioactive material on the test sample and must be performed by a person specifically authorized by the agency, the NRC, or another agreement state to perform the analysis. Should such testing reveal the presence of DU contamination, the exposure device must be removed from use until an evaluation of the wear of the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for

DU contamination while not in use and in storage. Before using or transferring such a device, however, the device must be tested for DU contamination, if the interval of storage exceeds 12 months. A record of the DU leak test must be made in accordance with 12VAC5-481-1420 .

12VAC5-481-1260. Quarterly Inventory.

A. Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation, and for devices containing depleted uranium received and possessed under the license.

B. The licensee or registrant shall maintain records of the quarterly inventory in accordance with 12VAC5-481-1430 .

12VAC5-481-1270. Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.

A. The licensee or registrant shall perform visual and operability checks on survey meters, radiation machines, radiographic exposure devices, transport and storage containers, associated equipment and source changers before each day's use, or work shift, to ensure that:

1. The equipment is in good working condition;

2. The sources are adequately shielded; and

3. Required labeling is present.

B. Survey instrument operability must be performed using check sources or other appropriate means.

C. If equipment problems are found, the equipment must be removed from service until repaired.

D. Each licensee or registrant shall have written procedures for and perform inspection and routine maintenance of radiation machines, radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed three months or before the first use thereafter to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment must be removed from service until repaired. Replacement components shall meet design requirements.

E. The licensee's inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

F. Records of equipment problems and of any maintenance performed under this section must be made in accordance with 12VAC5-481-1450 .

12VAC5-481-1280. Permanent Radiographic Installations.

A. Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have either:

1. An entrance control of the type described in 12VAC5-481-780 that causes the radiation level upon entry into the area to be reduced; or

2. Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal must be actuated by radiation whenever the source is exposed or the machine is energized. The audible signal must be actuated when an attempt is made to enter the installation while the source is exposed or the machine is energized.

B. The alarm system must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry as designated in subdivision A 1 of this section must be tested monthly. If an entrance control device or an alarm is operating improperly, it must be immediately labeled as defective and repaired within seven calendar days. The facility may continue to be used during this seven-day period, provided the licensee or registrant implements the continuous surveillance requirements of 12VAC5-481-1370 and uses an alarming ratemeter. Test records for entrance controls and audible and visual alarms must be maintained in accordance with 12VAC5-481-1460 .

12VAC5-481-1290. Labeling, Storage, and Transportation.

A. Licensees may not use a source changer or a container to store radioactive material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol conventional colors, i.e., magenta, purple, or black on a yellow background, having a minimum diameter of 25 mm, and the wording:

CAUTION *

RADIOACTIVE MATERIAL

NOTIFY CIVIL AUTHORITIES (or "NAME OF COMPANY")

* ——or "DANGER"

B. Licensees may not transport radioactive material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in Part XIII (12VAC5-481-2950 et seq.) of this chapter.

C. Radiographic exposure devices, source changers, storage containers, and radiation machines, shall be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store radioactive material in a manner that will minimize danger from explosion or fire.

D. Licensees shall lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

12VAC5-481-1300. Conducting Industrial Radiographic Operations.

Article 2. Radiation Safety Requirements

A. Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of 12VAC5-481-1320 C. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

B. All radiographic operations must be conducted in a permanent radiographic installation unless otherwise specifically authorized by the agency.

C. Except when physically impossible, collimators shall be used in industrial radiographic operations that use radiographic exposure devices that allow the source to be moved out of the device.

D. A licensee or registrant may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the agency, the NRC, or by another agreement state.

12VAC5-481-1310. Radiation Safety Officer.

A. The radiation safety officer shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's or registrant's program.

B. The minimum qualifications, training, and experience for radiation safety officers for industrial radiography are as follows:

1. Completion of the training and testing requirements of 12VAC5-481-1320 A;

2. 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

3. Formal training in the establishment and maintenance of a radiation protection program.

C. The agency will consider alternatives when the radiation safety officer has appropriate training and experience in the field of ionizing radiation, and in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

D. The specific duties and authorities of the radiation safety officer include:

1. Establishing and overseeing all operating, emergency, and ALARA procedures as required by Part IV (12VAC5-481-600 et seq.) of this chapter and reviewing them regularly to ensure that they conform to agency regulations and to the license or registration conditions;

2. Overseeing and approving the training program for radiographic personnel to ensure that appropriate and effective radiation protection practices are taught;

3. Ensuring that required radiation surveys and leak tests are performed and documented in accordance with the regulations, including any corrective measures when levels of radiation exceed established limits;

4. Ensuring that personnel monitoring devices are calibrated, if applicable, and used properly; that records are kept of the monitoring results; and that timely notifications are made as required by Part IV of this chapter; and

5. Ensuring that operations are conducted safely and for implementing corrective actions including terminating operations.

12VAC5-481-1320. Training.

A. The licensee or registrant may not permit any individual to act as a radiographer until the individual has received at least 40 hours of training in the subjects outlined in subsection G of this section in addition to on the job training consisting of hands-on experience under the supervision of a radiographer and is certified through a radiographer certification program by a certifying entity meeting the requirements of 10 CFR Part 34, Appendix A. The on-the-job training shall include a minimum of two months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material and/or one month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on-the-job training (3 months or 480 hours).

B. In addition, the licensee or registrant may not permit any individual to act as a radiographer until the individual:

1. Has received copies of and instruction in the requirements described in the regulations contained in this part, 12VAC5-481-30 and applicable sections of Parts IV (12VAC5-481-600 et seq.), X (12VAC5-481-2250 et seq.), and XIII (12VAC5-481-2950 et seq.) of this chapter, in the license or registration under which the radiographer will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;

2. Has demonstrated an understanding of items in subdivision 1 of this subsection by successful completion of a written examination;

3. Has received training in the use of the registrant's radiation machines, or the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

4. Has demonstrated understanding of the use of the equipment described in subdivision 3 of this subsection by successful completion of a practical examination.

C. The licensee or registrant may not permit any individual to act as a radiographer's assistant until the individual:

1. Has received copies of and instruction in the requirements described in the regulations contained in this part, 12VAC5-481-30 and applicable sections of Parts IV (12VAC5-481-600 et seq.), X (12VAC5-481-2250 et seq.), and XIII (12VAC5-481-2950 et seq.) of this chapter, in the license or registration under which the radiographer's assistant will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;

2. Has demonstrated an understanding of items in subdivision 1 of this subsection by successful completion of a written examination;

3. Under the personal supervision of a radiographer, has received training in the use of the registrant's radiation machines, or the licensee's radiographic exposure devices and sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

4. Has demonstrated understanding of the use of the equipment described in subdivision 3 of this subsection by successful completion of a practical examination.

D. The licensee or registrant shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

E. Except as provided in subdivision 4 of this subsection, the RSO or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the agency's regulations, license or registration requirements, and operating and emergency procedures are followed. The inspection program must:

1. Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed six months;

2. Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than six months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of subdivision B 3 of this section and the radiographer's assistant must demonstrate knowledge of the training requirements of subdivision C 3 of this section by a practical examination before these individuals can next participate in a radiographic operation;

3. The agency may consider alternatives in those situations where the individual serves as both radiographer and radiation safety officer; and

4. In those operations where a single individual serves as both radiographer and radiation safety officer, and performs all radiography operations, an inspection program is not required;

F. The licensee or registrant shall maintain records of the above training to include certification documents, writtenand practical examinations, refresher safety training and inspections of job performance in accordance with 12VAC5-481-1470 .

G. The licensee or registrant shall include the following subjects required in subsection A of

this section:

1. Fundamentals of radiation safety including:

   a. Characteristics of gamma and x-radiation;

   b. Units of radiation dose and quantity of radioactivity;

   c. Hazards of exposure to radiation;

   d. Levels of radiation from sources of radiation; and

   e. Methods of controlling radiation dose (time, distance, and shielding);

2. Radiation detection instruments including:

   a. Use, operation, calibration, and limitations of radiation survey instruments;

   b. Survey techniques; and

   c. Use of personnel monitoring equipment;

3. Equipment to be used including:

   a. Operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtails);

   b. Operation and control of radiation machines;

   c. Storage, control, and disposal of sources of radiation; and

   d. Inspection and maintenance of equipment.

4. The requirements of pertinent state and federal regulations; and

5. Case histories of accidents in radiography.

12VAC5-481-1330. Operating and Emergency Procedures.

A. Operating and emergency procedures must include, as a minimum, instructions in the following:

1. Appropriate handling and use of sources of radiation so that no person is likely to be exposed to radiation doses in excess of the limits established in Part IV (12VAC5-481-600 et seq.) of this chapter;

2. Methods and occasions for conducting radiation surveys;

3. Methods for posting and controlling access to radiographic areas;

4. Methods and occasions for locking and securing sources of radiation;

5. Personnel monitoring and the use of personnel monitoring equipment;

6. Transporting equipment to field locations, including packing of radiographic exposure

devices and storage containers in the vehicles, placarding of vehicles when required, and control of the equipment during transportation as described in Part XIII (12VAC5-481-2950 et seq.) of this chapter;

7. The inspection, maintenance, and operability checks of radiographic exposure devices, radiation machines, survey instruments, alarming ratemeters, transport containers, and storage containers;

8. Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarming ratemeter alarms unexpectedly;

9. The procedure(s) for identifying and reporting defects and noncompliance, as required by 12VAC5-481-1530;

10. The procedure for notifying proper persons in the event of an accident or incident;

11. Minimizing exposure of persons in the event of an accident or incident, including a source disconnect, a transport accident, or loss of a source of radiation;

12. Source recovery procedure if licensee will perform source recoveries; and

13. Maintenance of records.

B. The licensee or registrant shall maintain copies of current operating and emergency procedures in accordance with 12VAC5-481-1480 and 12VAC5-481-1520 .

12VAC5-481-1340. Supervision of Radiographer's Assistants.

The radiographer's assistant shall be under the personal supervision of a radiographer when using sources of radiation or conducting radiation surveys required by subdivision 2 of 12VAC5-481-1360 to determine that the sealed source has returned to the shielded position or the radiation machine is off after an exposure. The personal supervision must include:

1. The radiographer's physical presence at the site where the sources of radiation are being used;

2. The availability of the radiographer to give immediate assistance if required; and

3. The radiographer's direct observation of the assistant's performance of the operations referred to in this section.

12VAC5-481-1350. Personnel Monitoring.

A. The licensee or registrant may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a combination of direct reading dosimeter, an alarming ratemeter, and either a film badge, an optically stimulated luminescence (OSL) dosimeter or a thermoluminescent dosimeter (TLD). At permanent radiographic installations where other appropriate alarming or warning devices are in routine use, or during radiographic operations using radiation machines, the use of an alarming ratemeter is not required.

1. Pocket dosimeters must have a range from 0 to 2 mSv (200 mrem) and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

2. Each film badge, OSL or TLD must be assigned to and worn by only one individual.

3. Film badges must be exchanged monthly. OSLs or TLDs must be exchanged at periods not to exceed three months.

4. After replacement, each film badge, OSL or TLD must be returned to the supplier for processing within 14 calendar days of the end of the monitoring period, or as soon as practicable. In circumstances that make it impossible to return each film badge, OSL or TLD in 14 calendar days, such circumstances must be documented and available for review by the agency.

B. Direct reading dosimeters, such as pocket dosimeters or electronic personal dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with 12VAC5-481-1490 .

C. Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with 12VAC5-481-1490 . Acceptable dosimeters must read within plus or minus 20% of the true radiation exposure.

D. If an individual's pocket dosimeter is found to be off-scale, or the electronic personal dosimeter reads greater than 2 mSv (200 mrem), the individual's film badge, OSL or TLD must be sent for processing within 24 hours. In addition, the individual may not resume work associated with the use of sources of radiation until a determination of the individual's radiation exposure has been made. This determination must be made by the radiation safety officer or the radiation safety officer's designee. The results of this determination must be included in the records maintained in accordance with 12VAC5-481-1490 .

E. If a film badge, OSL or TLD is lost or damaged, the worker shall cease work immediately until a replacement film badge, OSL or TLD is provided and the exposure is calculated for the time period from issuance to loss or damage of the film badge, OSL or TLD. The results of the calculated exposure and the time period for which the film badge, OSL or TLD was lost or damaged must be included in the records maintained in accordance with 12VAC5-481-1490 .

F. Reports received from the film badge, OSL or TLD processor must be retained in accordance with 12VAC5-481-1490 .

G. Each alarming ratemeter must:

1. Be checked to ensure that the alarm functions properly before using at the start of each shift;

2. Be set to give an alarm signal at a preset dose rate of 5 mSv (500 mrem) per hour with an accuracy of plus or minus 20% of the true radiation dose rate;

3. Require special means to change the preset alarm function; and

4. Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee shall maintain records of alarming ratemeter calibrations in accordance with 12VAC5-481-1490 .

12VAC5-481-1360. Radiation Surveys.

The licensee or registrant shall:

1. Conduct all surveys with a calibrated and operable radiation survey instrument that meets the requirements of 12VAC5-481-1240;

2. Conduct a survey of the radiographic exposure device and the guide tube after each exposure when approaching the device or the guide tube. The survey must determine that the sealed source has returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment. Radiation machines shall be surveyed after each exposure to determine that the machine is off;

3. Conduct a survey of the radiographic exposure device whenever the source is exchanged and whenever a radiographic exposure device is placed in a storage area, as defined in 12VAC5-481-10 , to ensure that the sealed source is in its shielded position; and

4. Maintain records in accordance with 12VAC5-481-1500 .

12VAC5-481-1370. Surveillance.

During each radiographic operation, the radiographer shall ensure continuous direct visual surveillance of the operation to protect against unauthorized entry into a radiation area or a high radiation area, as defined in Part I (12VAC5-481-10 et seq.) of this chapter, except at permanent radiographic installations where all entryways are locked and the requirements of 12VAC5-481-1280 are met.

12VAC5-481-1380. Posting.

All areas in which industrial radiography is being performed must be conspicuously posted as required by 12VAC5-481-860 . The exceptions listed in 12VAC5-481-870 do not apply to industrial radiographic operations.

12VAC5-481-1390. Records for Industrial Radiography.

Article 3. Recordkeeping Requirements

Each licensee or registrant shall maintain a copy of its license or registration, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the agency, or until the agency terminates the license or registration.

12VAC5-481-1400. Records of Receipt and Transfer of Sources of Radiation.

A. Each licensee or registrant shall maintain records showing the receipts and transfers of sealed sources, devices using DU for shielding, and radiation machines, and retain each record for three years after it is made.

B. These records must include the date, the name of the individual making the record, radionuclide, number of becquerels (curies) or mass (for DU), and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

12VAC5-481-1410. Records of Radiation Survey Instruments.

Each licensee or registrant shall maintain records of the calibrations of its radiation survey instruments that are required under 12VAC5-481-1240 and retain each record for three years after it is made.

12VAC5-481-1420. Records of Leak Testing of Sealed Sources and Devices Containing Du.

Each licensee shall maintain records of leak test results for sealed sources and for devices containing DU. The results must be stated in units of becquerels (microcuries). The licensee shall retain each record for three years after it is made or until the source in storage is removed.

12VAC5-481-1430. Records of Quarterly Inventory.

A. Each licensee or registrant shall maintain records of the quarterly inventory of sources of radiation, including devices containing depleted uranium as required by 12VAC5-481-1260 , and retain each record for three years.

B. The record must include the date of the inventory, name of the individual conducting the inventory, radionuclide, number of becquerels (curies) or mass (for DU) in each device, location of sources of radiation and/or devices, and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

12VAC5-481-1440. Utilization Logs.

A. Each licensee or registrant shall maintain utilization logs showing for each source of radiation the following information:

1. A description, including the make, model, and serial number of the radiation machine or the radiographic exposure device, transport, or storage container in which the sealed source is located;

2. The identity and signature of the radiographer to whom assigned;

3. The location and dates of use, including the dates removed and returned to storage; and

4. For permanent radiographic installations, the dates each radiation machine is energized.

B. The licensee or registrant shall retain the logs required by subsection A of this section for three years.

12VAC5-481-1450. Records of Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers,

Associated Equipment, Source Changers, and Survey Instruments.

A. Each licensee or registrant shall maintain records specified in 12VAC5-481-1270 of equipment problems found in daily checks and quarterly inspections of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments, and retain each record for three years after it is made.

B. The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was performed.

12VAC5-481-1460. Records of Alarm System and Entrance Control Checks at Permanent Radiographic Installations.

Each licensee or registrant shall maintain records of alarm system and entrance control tests required by 12VAC5-481-1280 and retain each record for three years after it is made.

12VAC5-481-1470. Records of Training and Certification.

Each licensee or registrant shall maintain the following records for three years:

1. Records of training of each radiographer and each radiographer's assistant. The record must include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, the names of individuals conducting and receiving the oral and practical examinations, and a list of items tested and the results of the oral and practical examinations; and

2. Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any noncompliance observed by the radiation safety officer or designee.

12VAC5-481-1480. Copies of Operating and Emergency Procedures.

Each licensee or registrant shall maintain a copy of current operating and emergency procedures until the agency terminates the license or registration. Superseded material must be retained for three years after the change is made.

12VAC5-481-1490. Records of Personnel Monitoring.

Each licensee or registrant shall maintain the following exposure records specified in 12VAC5-481-1350 :

1. Direct reading dosimeter readings and yearly operability checks required by 12VAC5-481-1350 B and 12VAC5-481-1350 C for three years after the record is made;

2. Records of alarming ratemeter calibrations for three years after the record is made;

3. Reports received from the film badge, OSL or TLD processor until the agency terminates the license or registration; and

4. Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged film badges, OSL or TLD's, until the agency terminates the license or registration.

12VAC5-481-1500. Records of Radiation Surveys.

Each licensee shall maintain a record of each exposure device survey conducted before the device is placed in storage as specified in subdivision 3 of 12VAC5-481-1360 . Each record must be maintained for three years after it is made.

12VAC5-481-1510. Form of Records.

Each record required by this part must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

12VAC5-481-1520. Location of Documents and Records.

A. Each licensee or registrant shall maintain copies of records required by this part and other applicable parts of these regulations at the location specified in 12VAC5-481-1200 A 11.

B. Each licensee or registrant shall also maintain current copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite;

1. The license or registration authorizing the use of sources of radiation;

2. A copy of Parts I (12VAC5-481-10 et seq.); IV (12VAC5-481-600 et seq.); V (12VAC5-481-1170 et seq.); and X (12VAC5-481-2250 et seq.) of this chapter;

3. Utilization logs for each source of radiation dispatched from that location as required by 12VAC5-481-1440 .

4. Records of equipment problems identified in daily checks of equipment as required by 12VAC5-481-1450 A;

5. Records of alarm system and entrance control checks required by 12VAC5-481-1460 , if applicable;

6. Records of dosimeter readings as required by 12VAC5-481-1490;

7. Operating and emergency procedures as required by 12VAC5-481-1480;

8. Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by 12VAC5-481-1410;

9. Evidence of the latest calibrations of alarming ratemeters and operability checks of dosimeters as required by 12VAC5-481-1490;

10. Survey records as required by 12VAC5-481-1500 and 12VAC5-481-1000 as applicable, for the period of operation at the site;

11. The shipping papers for the transportation of radioactive materials required by Part XIII (12VAC5-481-2950 et seq.) of this chapter; and

12. When operating under reciprocity pursuant to Part III (12VAC5-481-380 et seq.) of this chapter, a copy of the applicable state license or registration, or NRC license authorizing the use of sources of radiation.

12VAC5-481-1530. Notifications.

Article 4. Notifications

A. In addition to the reporting requirements specified in 12VAC5-481-1110 and in Part IV (12VAC5-481-600 et seq.) of this chapter, each licensee or registrant shall provide a written report to the agency within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

1. Unintentional disconnection of the source assembly from the control cable;

2. Inability to retract the source assembly to its fully shielded position and secure it in this position;

3. Failure of any component, which is critical to safe operation of the device, to properly perform its intended function; or

4. An indicator on a radiation machine fails to show that radiation is being produced, an exposure switch fails to terminate production of radiation when turned to the off position, or a safety interlock fails to terminate X-ray production.

B. The licensee or registrant shall include the following information in each report submitted under subsection A of this section, and in each report of overexposure submitted under 12VAC5-481-1110 that involves failure of safety components of radiography equipment:

1. Description of the equipment problem;

2. Cause of each incident, if known;

3. Name of the manufacturer and model number of equipment involved in the incident;

4. Place, date, and time of the incident;

5. Actions taken to establish normal operations;

6. Corrective actions taken or planned to prevent recurrence; and

7. Names and qualifications of personnel involved in the incident.

C. Any licensee or registrant conducting radiographic operations or storing sources of radiation at any location not listed on the license or registration for a period in excess of 180 days in a calendar year shall notify the agency prior to exceeding the 180 days.

12VAC5-481-1540. (Repealed.)

Article 5. Jobsite Requirements

12VAC5-481-1550. (Repealed.)

12VAC5-481-1560. Reciprocity.

A. All reciprocal recognition of licenses and registrations by the agency will be granted in accordance with Part III (12VAC5-481-380 et seq.) of this chapter.

B. Reciprocal recognition by the agency of an individual radiographer certification will be granted provided that:

1. The individual holds a valid certification in the appropriate category issued by a certifying entity, as defined in 12VAC5-481-10;

2. The requirements and procedures of the certifying entity issuing the certification affords the same or comparable certification standards as those afforded by 12VAC5-481-1320 A;

3. The applicant presents the certification to the agency prior to entry into the state; and

4. No escalated enforcement action is pending with the NRC or in any other agreement state.

C. Certified individuals who are granted reciprocity by the agency shall maintain the certification upon which the reciprocal recognition was granted, or prior to the expiration of such certification, shall meet the requirements of 12VAC5-481-1320 A.

12VAC5-481-1570. Specific Requirements for Radiographic Personnel Performing Industrial Radiography.

A. At a job site, the following shall be supplied by the licensee or registrant:

1. At least one operable, calibrated survey instrument for each exposure device or radiation machine in use;

2. A current whole body personnel monitor (TLD, OSL or film badge) for each person performing radiographic operations;

3. An operable, calibrated pocket dosimeter with a range of 0 to 2 mSv (200 mrem) for each person performing radiographic operations;

4. An operable, calibrated, alarming ratemeter for each person performing radiographic

operations using a radiographic exposure device; and

5. The appropriate barrier ropes and signs.

B. Each radiographer at a job site shall have on their person a valid certification ID card issued by a certifying entity.

C. Industrial radiographic operations shall not be performed if any of the items in subsections A and B of this section are not available at the job site or are inoperable.

D. During an inspection, the agency may terminate an operation if any of the items in subsections A and B of this section are not available or operable, or if the required number of radiographic personnel are not present. Operations shall not be resumed until all required conditions are met.

12VAC5-481-1580. (Repealed.)

Part VI. Use Of Diagnostic X-Rays In The Healing Arts

12VAC5-481-1581. Purpose and Scope.

This part establishes requirements, for which a registrant is responsible, for use of diagnostic x-ray equipment and imaging systems by or under the supervision of an individual authorized by and licensed in accordance with Virginia law to engage in the healing arts or veterinary medicine. The provisions of this part are in addition to and not in substitution for other applicable provisions of this chapter.

12VAC5-481-1590. (Repealed.)

12VAC5-481-1591 General and Administrative Requirements

A. Radiation safety requirements. The registrant shall be responsible for directing the operation of the x-ray system under his administrative control. The registrant or the registrant's agent shall assure that the requirements of this chapter are met in the operation of the x-ray system or systems.

1. An x-ray system that does not meet the provisions of this chapter shall not be operated for diagnostic purposes.

2. Individuals who will be operating the x-ray systems shall meet the qualifications of this part to conduct the practice of radiologic technology.

3. A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel that specifies, for all examinations performed with that system, the following information:

a. Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;

b. Type and size of the image receptor to be used;

c. Type and size of the image receptor combination to be used, if any;

d. Source to image receptor distance to be used (except for dental intraoral radiography);

e. Type and location of placement of patient shielding (e.g., gonad, etc.) to be used; and

f. For mammography, indication of kVp/target/filter combination.

4. The registrant of a facility shall create and make available to x-ray operators written safety procedures, including patient holding and any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

5. Except for patients who cannot be moved out of the room, only the staff, ancillary personnel, or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

a. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 mm lead equivalent material;

b. The x-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 mm lead equivalent material. However, when distances provide sufficient protection from scatter radiation, or for low dose rate devices such as bone densitometry equipment, no protective devices may be necessary; and

c. Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 mm lead equivalent material or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.

6. Gonad shielding of not less than 0.5 mm lead equivalent material shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

7. Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

a. Exposure of an individual for training, demonstration, or other non-healing arts purposes; and

b. Exposure of an individual for the purpose of healing arts screening except as authorized by subdivision 11 of this subsection.

8. When a patient or image receptor must be provided with auxiliary support during a radiation exposure:

a. Mechanical holding devices shall be used when the technique permits. The written

safety procedures, as required by subdivision 4 of this subsection, shall list individual projections where holding devices cannot be utilized;

b. Written safety procedures, as required by subdivision 4 of this subsection, shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

c. The human holder shall be instructed in personal radiation safety and protected as required by subdivision 5 of this subsection. Caregivers who stay in the room to assist with imaging of patients shall be positioned and instructed to keep the protective apron between themselves and the patient;

d. No individual shall be used routinely to hold image receptors or patients;

e. In those cases where the patient must hold the image receptor, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 mm lead equivalent material; and

f. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection for all personnel who are involved with x-ray operations and who are otherwise not shielded.

9. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

a. The fastest imaging system consistent with the diagnostic objective of the examinations shall be used. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intraoral use in dental radiography.

b. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

c. Portable or mobile radiographic (exclude fluoroscopic) x-ray equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary x-ray installation.

d. X-ray systems subject to 12VAC5-481-1621 shall not be utilized in procedures where the source to patient distance is less than 30 cm, except for veterinary systems.

e. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

(1) Be positioned properly, that is, tube side facing the right direction, and grid centered to the central ray; and

(2) If the grid is of the focused type, be of the proper focal distance for the SIDs being used.

10. All individuals who are associated with the operation of an x-ray system are subject to

the requirements of 12VAC5-481-640 , 12VAC5-481-700 , and 12VAC5-481-710 .

11. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the agency. If any information submitted to the agency becomes invalid or outdated, the agency shall be immediately notified. Persons requesting that the agency approve a healing arts screening program shall submit the following information and evaluation:

a. Name and address of the applicant and, where applicable, the names and addresses of agents within this state;

b. Diseases or conditions for which the x-ray examinations are to be used in diagnoses;

c. A description of the x-ray examinations proposed in the screening program, that is, type and number of views;

d. Description of the population to be examined in the screening program, that is, age range, sex, physical condition, and other appropriate information;

e. An evaluation of any known alternate methods not involving ionizing radiation that could achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations;

f. An evaluation by a qualified medical physicist of the x-ray system or systems to be used in the screening program. The evaluation shall include the following:

(1) Documentation that such systems satisfy all requirements of this chapter; and

(2) Measurement of patient exposures from the x-ray examinations to be performed;

g. A description of the diagnostic x-ray quality control program;

h. A copy of the technique chart for the x-ray examination procedures to be used;

i. The qualifications of each individual who will be operating the x-ray system or systems;

j. The qualifications of the individual who will be supervising the operators of the x-ray system or systems. The extent of supervision and the method of work performance evaluation shall be specified;

k. The name and address of the practitioner licensed in the state who will interpret the radiograph;

l. Procedures to be used in advising the individuals screened and their practitioners of the healing arts or health care providers of the results of the screening procedure and any further medical needs indicated;

m. Procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations;

n. Frequency of screening of individuals; and

o. The duration of the screening program.

12. The registrant shall maintain the following information and maintenance record for each x-ray system for inspection by the agency:

a. Model and serial numbers of all major components, and user's manuals for those components;

b. Tube rating charts and cooling curves;

c. Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system or systems; and

d. A copy of all correspondence with the agency regarding that x-ray system.

13. Except for veterinary facilities, each facility shall maintain an x-ray utilization log containing the patient's name, the type of examination, and the date the examination was performed.

14. The registrant shall maintain a list of x-ray operators for each facility. Operators must be licensed by the Department of Health Professions where x-rays are used within the scope of practice or be certified by the American Registry of Radiological Technologists (ARRT), or be an individual enrolled, or was enrolled within the past three months, in an accredited program for radiologic technology and under the supervision of a licensed or certified radiological technologist, or if a dental assistant, comply with the Board of Dentistry's radiation certification requirements in 18VAC60-20-195 .

B. X-ray film processing facilities and practices.

1. Each installation using a radiographic x-ray system and analog image receptors (e.g., radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

a. Manually developed film.

(1) Processing tanks shall be constructed of mechanically rigid, corrosion resistant material; and

(2) The temperature of solutions in the tanks shall be maintained within the range of 60°F to 80°F (16°C to 27°C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer or, in the absence of such recommendations, with the following time-temperature chart:

Time-Temperature Chart		
Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
°C	°F	
26.7	80	2

26.1	79	2
25.6	78	2-1/2
25.0	77	2-1/2
24.4	76	3
23.9	75	3
23.3	74	3-1/2
22.8	73	3-1/2
22.2	72	4
21.7	71	4
21.1	70	4-1/2
20.6	69	4-1/2
20.0	68	5
19.4	67	5-1/2
18.9	66	5-1/2
18.3	65	6
17.8	64	6-1/2
17.2	63	7
16.7	62	8
16.1	61	8-1/2
15.6	60	9-1/2

(3) Devices shall be utilized that will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

b. Automatic processors and other closed processing systems. Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer. In the absence of such recommendations, the film shall be developed using the following chart:

Developer Temperature		Minimum Immersion Time*
°C	°F	Seconds
35.5	96	19
35	95	20

34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30

*Immersion time only, no crossover time included.

Processing deviations from the requirements of this subdivision shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing and special rapid chemistry).

2. Other requirements.

a. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

b. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-ray radiation sufficient to produce an optical density from one to two when processed shall not suffer an increase in density greater than 0.1 (0.05 for mammography) when exposed in the darkroom for two minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

c. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

d. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

e. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.

f. Outdated x-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

g. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer and shall be maintained in strength by replenishment or renewal

so that full development is accomplished within the time specified by the manufacturer.

h. Living and deceased patients' diagnostic images shall be maintained for a minimum of five years. Diagnostic images for minors shall be maintained for a minimum of five years beyond their 18th birthday.

C. The registrant shall submit to the agency a copy of all surveys, calibrations, and inspections performed by a private inspector within 30 days of completion of the survey, calibration, or inspection.

D. The private inspector shall provide the inspection report to the registrant within 14 days of the completion of the inspection. A summary or recommendation shall be included with this report. The inspector shall notify the registrant of any noncompliances that need corrective action.

E. Violations identified as "serious" must be corrected within 30 days. Certification of the unit will not be issued until the violation is corrected. Violations identified as "non-serious" shall be corrected before the next inspection cycle. Uncorrected "non-serious" violations will become "serious" and require immediate correction.

12VAC5-481-1600. (Repealed.)

12VAC5-481-1601. General Requirements for All Diagnostic X-Ray Systems.

In addition to other requirements of this part, all diagnostic x-ray systems shall meet the following requirements:

1. Warning label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view:

"WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions, and maintenance schedules are observed."

2. Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 0.88 milligray (mGy) air kerma (100 milliroentgen (mR) exposure) in one hour when the x-ray tube is operated at its leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

3. Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed an air kerma of 18 microgray (two milliroentgens exposure) in one hour at five cm from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater

than 20 cm.

4. Beam quality half-value layer (HVL).

a. The HVL of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table 1 (i)under the heading "Specified Dental Systems" for any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980; (ii)under the heading "I-Other X-Ray Systems" for any dental x-ray system designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006; and (iii)under the heading "II-Other X-Ray Systems" for all x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006. If it is necessary to determine such half-value layer at an x-ray tube potential that is not listed in Table 1, linear interpolation or extrapolation may be made. Positive means shall be provided to ensure that at least the minimum filtration needed to achieve beam quality requirements is in the useful beam during each exposure. In the case of a system, which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlocked with the kilovoltage selector that will prevent x-ray emissions if the minimum required filtration is not in place.

TABLE 1

X-Ray Tube Voltage (kilovolt peak)				
Design Operating Range	Measured Operating Potential	Minimum HVL (mm in Aluminum)		
		Specified Dental Systems[1]	I-Other X-Ray Systems[2]	II-Other X-Ray Systems[3]
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3

130	3.5	3.5	4.7
140	3.8	3.8	5.0
150	4.1	4.1	5.4

[1] Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.

[2] Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006.

[3] All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.

b. Optional filtration. Fluoroscopic systems manufactured on or after June 10, 2006, incorporating an x-ray tube or tubes with a continuous output of one kilowatt or more and an anode heat storage capacity of one million heat units or more shall provide the option of adding x-ray filtration to the diagnostic source assembly in addition to the amount needed to meet the half-value layer provisions in Table 1. The selection of this additional x-ray filtration shall be either at the option of the user or automatic as part of the selected mode of operation. A means of indicating which combination of additional filtration is in the x-ray beam shall be provided.

c. Measuring compliance. For capacitor energy storage equipment, compliance shall be determined with the maximum selectable quantity of charge per exposure.

5. Aluminum equivalent of material between patient and image receptor. Except when used in a CT x-ray system, the aluminum equivalent of each of the items listed in Table 2, which are used between the patient and the image receptor, shall not exceed the indicated limits. Compliance shall be determined by x-ray measurements made at a potential of 100 kilovolts peak and with an x-ray beam that has an HVL specified in Table 1 for the potential. This requirement applies to front panel or panels of cassette holders and film changers provided by the manufacturer for patient support or for prevention of foreign object intrusions. It does not apply to screens and their associated mechanical support panels or grids.

TABLE 2

Item	Maximum Aluminum Equivalent (mm)
Front panel(s) of cassette holders (total of all)	1.2
Film panel(s) of film changer (total of all)	1.2
Cradle	2.3

Tabletop, stationary, without articulated joints	1.2
Tabletop, movable, without articulated joints (including stationary subtop)	1.7
Tabletop, with radiolucent panel having one articulated joint	1.7
Tabletop, with radiolucent panel having two or more articulated joints	2.3
Tabletop, cantilevered	2.3
Tabletop, radiation therapy simulator	5.0

6. Battery charge indicator. On battery-powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

7. Modification of certified diagnostic x-ray components and systems.

a. Diagnostic x-ray components and systems certified in accordance with 21 CFR Part 1020 shall not be modified such that the component or system fails to comply with any applicable provision of this part.

b. The owner of a diagnostic x-ray system who uses the system in a professional or commercial capacity may modify the system provided the modification does not result in the failure of the system or a component to comply with the applicable requirements of this part. The owner who causes such modification need not submit the reports required by this part, provided the owner records the date and the details of the modification in the system records and maintains this information, and provided the modification of the x-ray system does not result in a failure to comply with this part.

8. Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes that have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

9. Mechanical support of tube head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

10. Technique indicators.

a. For x-ray equipment capable of displaying technique factors, the technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors that are set prior to the exposure shall be indicated.

b. The requirement of subdivision 10 a of this subsection may be met by permanent

markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

11. Maintaining compliance. Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal X-Ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.

12. Locks. All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.

13. Mechanical timers. The use of mechanical timers is prohibited.

12VAC5-481-1610. (Repealed.)

12VAC5-481-1611. Fluoroscopic Equipment.

A. The provisions of this sectionapply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, except computed tomography x-ray systems manufactured on or after November 29, 1984.

B. Primary protective barrier.

1. Limitation of useful beam. The fluoroscopic imaging assembly shall be provided with a primary protective barrier that intercepts the entire cross section of the useful beam at any SID. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam. The AKR due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the fluoroscopic imaging receptor shall not exceed $3.34x10^{-3}$% of the entrance AKR, at a distance of 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor. Radiation therapy simulation systems shall be exempt from this requirement provided the systems are intended only for remote control operation.

2. Measuring compliance. The AKR shall be measured in accordance with subsection E of this section. The AKR due to transmission through the primary barrier combined with radiation from the fluoroscopic image receptor shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 cm above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 cm. Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam 10 cm from the point of measurement of entrance AKR and between this point and the input surface of the fluoroscopic imaging assembly.

C. Field limitation.

1. Angulation. For fluoroscopic equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance with subdivisions 4 and 5 of this subsection shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

2. Further means for limitation. Means shall be provided to permit further limitation of the x-ray field to sizes smaller than the limits of subdivisions 4 and 5 of this subsection. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or capability of a visible area of greater than 300 square cm, shall be provided with means for stepless adjustment of the x-ray field. Equipment with a fixed SID and the capability of a visible area of no greater than 300 square cm shall be provided with either stepless adjustment of the x-ray field or with a means to further limit the x-ray field size at the plane of the image receptor to 125 square cm or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size containable in a square of five cm by five cm. This paragraph does not apply to non-image-intensified fluoroscopy.

3. Non-image-intensified fluoroscopy. The x-ray field produced by non-image-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided for stepless adjustment of field size. The minimum field size, at the greatest SID, shall be containable in a square of five cm by five cm.

4. Fluoroscopy and radiography using the fluoroscopic imaging assembly with inherently circular image receptors.

a. For fluoroscopic equipment manufactured before June 10, 2006, other than radiation therapy simulation systems, the following applies:

(1) Neither the length nor width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3.0% of the SID. The sum of the excess length and the excess width shall be no greater than 4.0% of the SID.

(2) For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field that pass through the center of the visible area of the image receptor.

b. For fluoroscopic equipment manufactured on or after June 10, 2006, other than radiation simulation systems, the maximum area of the x-ray field in the plane of the image receptor shall conform with one of the following requirements:

(1) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to 34 cm in any direction, at least 80% of the area of the x-ray field overlaps the visible area of the image receptor; or

(2) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than 34 cm in any direction, the x-ray field measured along the direction of greatest misalignment with the visible area of the image receptor does not extend beyond the edge of the visible area of the image receptor by more than two cm.

5. Fluoroscopy and radiography using fluoroscopic imaging assembly with inherently rectangular image receptors. For x-ray systems manufactured on or after June 10, 2006, the following applies:

a. Neither the length nor width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3.0% of the SID. The sum of the excess length and the excess width shall be no greater than 4.0% of the SID.

b. The error in alignment shall be determined along the length and width dimensions of the x-ray field that pass through the center of the visible area of the image receptor.

If the fluoroscopic x-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch shall be clearly labeled as follows:

"For X-Ray Field Limitation System Failure"

D. Activation of tube. X-ray production in the fluoroscopic mode shall be controlled by a device that requires continuous pressure by the operator for the entire time of any exposure. When recording serial radiographic images from the fluoroscopic image receptor, the operator shall be able to terminate the x-ray exposure or exposures at any time, but means may be provided to permit completion of any single exposure of the series in process.

E. Air kerma rates. For fluoroscopic equipment, the following requirements apply:

1. Fluoroscopic equipment manufactured before May 19, 1995.

a. Equipment provided with automatic exposure rate control (AERC) shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min exposure rate) at the measurement point specified in subdivision 3 of this subsection, except as specified in subdivision 1 e of this subsection.

b. Equipment provided without AERC shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 44 mGy per minute (5 R/min exposure rate) at the measurement point specified in subdivision 3 of this subsection, except as specified in subdivision 1 e of this subsection.

c. Equipment provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min exposure rate) in either mode at the

measurement point specified in subdivision 3 of this subsection, except as specified in subdivision 1 e of this subsection.

d. Equipment may be modified in accordance with this partto comply with subdivision 2 of this subsection. When the equipment is modified, it shall bear a label indicating the date of the modification and the statement:

"Modified to comply with 21 CFR 1020.32(h)(2)"

e. Exceptions:

(1) During recording of fluoroscopic images; or

(2) When a mode of operation has an optional high-level control, in which case that mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of any of the rates specified in subdivisions 1 a, b, and c of this subsectionat the measurement point specified in subdivision 3 of this subsection, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

2. Fluoroscopic equipment manufactured on or after May 19, 1995.

a. Equipment shall be equipped with AERC if operable at any combination of tube potential and current that results in an AKR greater than 44 mGy per minute (5 R/min exposure rate) at the measurement point specified in subdivision 3 of this subsection. Provision or manual selection of technique factors may be provided.

b. Equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min exposure rate) at the measurement point specified in subdivision 3 of this subsection, except as specified in subdivision 2 c of this subsection.

c. Exceptions:

(1) For equipment manufactured prior to June 10, 2006, during the recording of images from the fluoroscopic image receptor using photographic film or a video camera when the x-ray source is operated in a pulsed mode.

(2) For equipment manufactured on or after June 10, 2006, during the recording of images from the fluoroscopic image receptor for the purpose of providing the user with a recorded image or images after termination of the exposure. Such recording does not include images resulting from a last-image-hold feature that are not recorded.

(3) When a mode of operation has an optional high-level control and the control is activated, in which case the equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 176 mGy per minute (20 R/min exposure rate) at the measurement point specified in subdivision 3 of this subsection. Special means of activation of high-level controls shall be required. The

high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is employed.

3. Measuring compliance. Compliance with this subsection shall be determined as follows:

a. If the source is below the x-ray table, the AKR shall be measured at one cm above the tabletop or cradle.

b. If the source is above the x-ray table, the AKR shall be measured at 30 cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

c. In a C-arm type of fluoroscope, the AKR shall be measured at 30 cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 cm from the input surface of the fluoroscopic imaging assembly.

d. In a C-arm type of fluoroscope having an SID less than 45 cm, the AKR shall be measured at the minimum SSD.

e. In a lateral type of fluoroscope, the air kerma rate shall be measured at a point 15 cm from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 cm to the centerline of the x-ray table.

4. Exemptions. Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in this subsection when used for therapy simulation purposes.

F. (Reserved.)

G. Indication of potential and current. During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated. Deviation of x-ray tube potential and current from the indicated value shall not exceed the maximum deviation as stated by the manufacturer.

H. Source-skin distance.

1. Means shall be provided to limit the source-skin distance to not less than 38 cm on stationary fluoroscopes and to not less than 30 cm on mobile and portable fluoroscopes. In addition, for fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this subsection, provisions may be made for operating at shorter source-skin distances but in no case less than 20 cm.

2. For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than 45 cm, means shall be provided to limit the source-skin distance to not less than 19 cm. Such systems shall be labeled for extremity use only. In addition, for those systems intended for

specific surgical application that would be prohibited at the source-skin distance specified in this subsection, provisions may be made for operation at shorter source-skin distances but in no case less than 10 cm.

I. Fluoroscopic irradiation time, display, and signal.

1. Fluoroscopic equipment manufactured before June 10, 2006.

a. Equipment shall be provided with means to preset the cumulative irradiation time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative irradiation time. Such signal shall continue to sound while x-rays are produced until the timing device is reset. Fluoroscopic equipment may be modified in accordance with 21 CFR 1020.30(q) to comply with the requirements of this subdivision. When the equipment is modified, it shall bear a label indicating the statement:

"Modified to comply with 21 CFR 1020.32(h)(2)"

b. As an alternative to the requirements of this subsection, radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between x-ray examinations.

2. For x-ray controls manufactured on or after June 10, 2006, there shall be provided for each fluoroscopic tube:

a. A display of the fluoroscopic irradiation time at the fluoroscopist's working position. This display shall function independently of the audible signal described in this subsection. The following requirements apply:

(1) When the x-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least once every six seconds.

(2) The fluoroscopic irradiation time shall also be displayed within six seconds of termination of an exposure and remain displayed until reset.

(3) Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure.

b. A signal audible to the fluoroscopist shall sound for each passage of five minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least two seconds.

J. Mobile and portable fluoroscopes. In addition to the other requirements of this subsection, mobile and portable fluoroscopes shall provide an image receptor incorporating more than a simple fluorescent screen.

K. Display of last-image-hold (LIH). Fluoroscopic equipment manufactured on or after June

10, 2006, shall be equipped with means to display LIH image following termination of the fluoroscopic exposure.

1. For an LIH image obtained by retaining pretermination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection shall be indicated prior to initiation of the fluoroscopic exposure.

2. For an LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the technique factors for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure.

3. Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.

L. Displays of values of AKR and cumulative air kerma. Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist's working position the AKR and cumulative air kerma. The following requirements apply for each x-ray tube used during an examination or procedure:

1. When the x-ray tube is activated and the number of images produced per unit time is greater than six images per second, the AKR in mGy/min shall be continuously displayed and updated at least once every second.

2. The cumulative air kerma in units of mGy shall be displayed either within five seconds of termination of an exposure or displayed continuously and updated at least once every five seconds.

3. The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma.

4. The AKR and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope.

a. For fluoroscopes with x-ray source below the x-ray table, x-ray source above the table, or of lateral type, the reference location shall be the respective locations specified in subdivision E 3 a or E 3 e of this section.

b. For C-arm fluoroscopes, the reference location shall be 15 cm from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin.

5. Means shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.

6. The displayed AKR and cumulative air kerma shall not deviate from the actual values by

more than ±35% over the range of six mGy/min and 100 mGy to the maximum indication of AKR and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than three seconds.

M. Control of scattered radiation.

1. Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation that originates from under the table. The attenuation required shall be not less than 0.25 mm lead equivalent.

2. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

a. Is at least 120 centimeters from the center of the useful beam; or

b. The radiation has passed through not less than 0.25 mm lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 12VAC5-481-1591 A 5.

3. The agency may grant exemptions to subdivision 2 of this subsection where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the agency shall not permit such exemption.

N. Operator qualifications. The facility shall ensure that only a licensed practitioner of the healing arts or a radiologic technologist or equivalent be allowed to operate fluoroscopic x-ray systems.

O. Equipment operation.

1. All imaging formed by the use of fluoroscopic x-ray systems shall be viewed, directly or indirectly, and interpreted by a licensed practitioner of the healing arts.

2. The operation of fluoroscopic x-ray systems by radiologic technologists or equivalent shall be performed under the direct supervision of a licensed practitioner of the healing arts.

3. Radiologic technology students shall not be allowed to operate fluoroscopic x-ray systems unless directly supervised by a licensed practitioner of the healing arts or radiologic technologist as specified in subsection N of this section.

4. Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

5. Facilities shall maintain a record of the cumulative fluoroscopic exposure time used and the number of fluorographic images recorded for each examination. This record shall include patient identification, type and date of examination, the fluoroscopic system used,

and operator's name.

P. Surveys. Radiation safety and equipment performance surveys shall be performed annually on all fluoroscopic x-ray systems by or under the direct supervision of a private or state inspector who is physically present at the facility during the inspection in order to assure compliance with these regulations.

12VAC5-481-1620. (Repealed.)

12VAC5-481-1621. Radiographic Equipment.

A. Control and indication of technique factors.

1. Visual indication. The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors that are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

2. Timers. Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

a. Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second. Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

b. During serial radiography, the operator shall be able to terminate the x-ray exposure at any time, but means may be provided to permit completion of any single exposure of the series in process.

3. Automatic exposure controls. When an automatic exposure control is provided:

a. Indication shall be made on the control panel when this mode of operation is selected;

b. When the x-ray tube potential is equal to or greater than 51 kilovolts peak (kVp), the minimum exposure time for field emission equipment rated for pulse operation shall be equal to or less than a time interval equivalent to two pulses and the minimum exposure time for all other equipment shall be equal to or less than 1/60 second or a time interval required to deliver five milliampere-seconds (mAs), whichever is greater;

c. Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kilowatt-seconds (kWs) per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure, except when the x-ray tube potential is less than 51 kVp, in which case the

product of x-ray tube current and exposure time shall be limited to not more than 2,000 mAs per exposure; and

d. A visible signal shall indicate when an exposure has been terminated at the limits described in subdivision 3 c of this subsection, and manual resetting shall be required before further automatically timed exposures can be made.

4. Accuracy. Deviation of technique factors from indicated values shall not exceed the limits given by the manufacturer. In the absence of manufacturer's limits, the deviation shall not exceed 10% of the indicated value for kVp and time.

B. Reproducibility. The following requirements shall apply when the equipment is operated on an adequate power supply as specified by the manufacturer:

1. Coefficient of variation. For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma shall be no greater than 0.10.

2. Measuring compliance. Determination of compliance shall be based on four consecutive measurements taken within a time period of one hour. Equipment manufactured after September 5, 1978, shall be subject to the additional requirement that all variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement. The percent line-voltage regulation shall be within ±1 of the mean value for all measurements. For equipment having automatic exposure controls, compliance shall be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of 12 pulses on field emission equipment rated for pulsed operation or no less than one-tenth second per exposure on all other equipment.

C. Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer in accordance with 21 CFR Part 1020 for any fixed x-ray tube potential within the range of 40% to 100% of the maximum rated.

1. Equipment having independent selection of x-ray tube current (mA). The average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. This is:

$|X1 - X2| \ 0.10(X1 + X2)$

where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

2. Equipment having selection of x-ray tube current-exposure time product (mAs). For equipment manufactured after May 3, 1994, the average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum. This is:

$|X1 - X2| \ 0.10(X1 + X2)$

where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs

selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

3. Measuring compliance. Determination of compliance shall be based on four exposures, made within one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 mm and the other is greater than 0.45 mm. For purposes of this requirement, focal spot size is the focal spot size specified by the x-ray tube manufacturer. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation at any one combination of technique factors shall be within ±1 of the mean value for all measurements at these technique factors.

D. Field limitation and alignment for mobile, portable, and stationary general purpose x-ray systems. Except when spot-film devices are in service, mobile, portable, and stationary general purpose radiographic x-ray systems shall meet the following requirements:

1. Variable x-ray field limitation. A means for stepless adjustment of the size of the x-ray field shall be provided. Each dimension of the minimum field size at an SID of 100 cm shall be equal to or less than five cm.

2. Visual definition.

a. Means for visually defining the perimeter of the x-ray field shall be provided. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2.0% of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

b. When a light localizer is used to define the x-ray field, it shall provide an average illuminance of not less than 10 foot-candles at 100 cm or at the maximum SID, whichever is less. The average illuminance shall be based on measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.

c. The edge of the light field at 100 cm or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than four in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than three in the case of beam-limiting devices designed for use on mobile and portable equipment. The contrast ratio is defined as I_1/I_2, where I_1 is the illuminance three mm from the edge of the light field toward the center of the field, and I_2 is the illuminance three mm from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of one mm.

E. Field indication and alignment on stationary general purpose x-ray equipment. Except when spot-film devices are in service, stationary general purpose x-ray systems shall meet the following requirements in addition to those prescribed in subsection D of this section:

1. Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to

the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2.0% of the SID and to indicate the SID to within 2.0%;

2. The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;

3. Indication of field size dimensions and SIDs shall be specified in centimeters or inches and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor that correspond to those indicated by the beam-limiting device to within 2.0% of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and

4. Compliance measurements will be made at discrete SIDs and image receptor dimensions in common clinical use (such as SIDs of 100, 150, and 200 cm or 36, 40, 48, and 72 inches and nominal image receptor dimensions of 13, 18, 24, 30, 35, 40, and 43 cm or 5, 7, 8, 9, 10, 11, 12, 14, and 17 inches) or at any other specific dimensions at which the beam-limiting device or its associated diagnostic x-ray system is uniquely designed to operate.

F. Field limitation on radiographic x-ray equipment other than general purpose radiographic systems.

1. Equipment for use with intraoral image receptors. Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

a. If the minimum - source-skin distance (SSD) is 18 cm or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than seven cm; and

b. If the minimum SSD is less than 18 cm, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than six cm.

For dental intraoral uses, an open ended shielded positioning device shall be used.

2. X-ray systems designed for one image receptor size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor and to align the center of the x-ray field with the center of image receptor to within 2.0% of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond the edge of the image receptor.

3. Systems designed for mammography.

a. Radiographic systems designed only for mammography and general purpose radiography systems, when special attachments for mammography are in service, manufactured on or after November 1, 1977, and before September 30, 1999, shall be provided with means to limit the useful beam such that the x-ray field at the plane of

the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2.0% of the SID. This requirement can be met with a system that performs as prescribed in subdivisions 4 a, b, and c of this subsection. When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in subdivisions 4 b and c of this subsection shall be the maximum SID for which the beam-limiting device or aperture is designed.

b. Mammographic beam-limiting devices manufactured on or after September 30, 1999, shall be provided with a means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor by more than 2.0% of the SID. This requirement can be met with a system that performs as prescribed in subdivisions 4 a, b, and c of this subsection. For systems that allow changes in SID, the SID indication specified in subdivisions 4 b and c of this subsection shall be the maximum SID for which the beam-limiting device or aperture is designed.

c. Each image receptor support device manufactured on or after November 1, 1977, intended for installation on a system designed for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

4. Other x-ray systems. Radiographic systems not specifically covered in subsections D, E, and H of this section, which are also designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2.0% of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2.0% of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

a. A system that performs in accordance with subsections D and E of this section; or when alignment means are also provided, may be met with either;

b. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

c. A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

G. Positive beam limitation (PBL). The requirements of this subsection shall apply to radiographic systems that contain PBL.

1. Field size. When a PBL system is provided, it shall prevent x-ray production when:

a. Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than 3.0% of the SID; or

b. The sum of the length and width differences stated in subdivision 1 a of this subsection without regard to sign exceeds 4.0% of the SID.

c. The beam-limiting device is at an SID for which PBL is not designed for sizing.

2. Conditions for PBL. When provided, the PBL system shall function as described in subdivision 1 of this subsection whenever all the following conditions are met:

a. The image receptor is inserted into a permanently mounted cassette holder;

b. The image receptor length and width are less than 50 cm;

c. The x-ray beam axis is within ±3 degrees of vertical and the SID is 90 cm to 130 cm inclusive; or the x-ray beam axis is within ±3 degrees of horizontal and the SID is 90 cm to 205 cm inclusive;

d. The x-ray beam axis is perpendicular to the plane of the image receptor to within ±3 degrees; and

e. Neither tomographic nor stereoscopic radiography is being performed.

3. Measuring compliance. Compliance with the requirements of subdivision 1 of this subsection shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of subdivision 2 of this subsection are met. Compliance shall be determined no sooner than five seconds after insertion of the image receptor.

4. Operator initiated undersizing. The PBL system shall be capable of operating such that, at the discretion of the operator, the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. Each dimension of the minimum field size at an SID of 100 cm shall be equal to or less than five cm. Return to PBL function as described in subdivision 1 of this subsection shall occur automatically upon any change of image receptor size or SID.

5. Override of PBL. A capability may be provided for overriding PBL in case of system failure and for servicing the system. This override may be for all SIDs and image receptor sizes. A key shall be required for any override capability that is accessible to the operator. It shall not be possible to remove the key while PBL is overridden. Each such key switch or key shall be clearly and durably labeled as follows:

"For X-Ray Field Limitation System Failure"

The override capability is considered accessible to the operator if it is referenced in the

operator's manual or in other material intended for the operator or if its location is such that the operator would consider it part of the operational controls.

H. Field limitation and alignment for spot-film devices. The following requirements shall apply to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system:

1. Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor that has been selected on the spot-film selector. Such adjustment shall be accomplished automatically when the x-ray field size in the plane of the image receptor is greater than the selected portion of the image receptor. If the x-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.

2. Neither the length nor width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3.0% of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4.0% of the SID. On spot film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

3. The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within 2.0% of the SID.

4. Means shall be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

a. For spot-film devices used on fixed-SID fluoroscopic systems that are not required to and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed 125 square cm; or

b. For spot-film devices used on fluoroscopic systems that have a variable SID or stepless adjustment of the field size, the minimum field size, at the greatest SID, shall be containable in a square of five cm by five cm.

5. A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic x-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows:

"For X-ray Field Limitation System Failure"

I. Source-skin distance.

1. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-skin distance to not less than:

a. 18 cm if operable above 50 kVp; or

b. 10 cm if not operable above 50 kVp.

2. Mobile and portable x-ray systems other than dental shall be provided with means to limit the source-skin distance to not less than 30 cm.

J. Beam-on indicators. The x-ray control shall provide visual indication whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

K. (Reserved.)

L. Radiation from capacitor energy storage equipment. Radiation emitted from the x-ray tube shall not exceed:

1. An air kerma of 0.26 microGy (0.03 mR exposure) in one minute at five cm from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated. Compliance shall be determined by measurements averaged over an area of 100 square cm, with no linear dimensions greater than 20 cm: and

2. An air kerma of 0.88 mGy (100 mR exposure) in one hour at 100 cm from the x-ray source, with beam-limiting device fully open, when the system is discharged through the x-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power. Compliance shall be determined by measurements of the maximum air kerma per discharge multiplied by the total number of discharges in one hour (duty cycle). The measurements shall be averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

M. Primary protective barrier for mammography x-ray systems.

1. For x-ray systems manufactured after September 5, 1978, and before September 30, 1999, which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the air kerma five cm from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.88 microGy (0.1 mR exposure) for each activation of the tube.

2. For mammographic x-ray systems manufactured on or after September 30, 1999:

a. At any SID where exposures can be made, the image receptor support device shall provide a primary protective barrier that intercepts the cross section of the useful beam along every direction except at the chest wall edge.

b. The x-ray system shall not permit exposure unless the appropriate barrier is in place to intercept the useful beam as required in subdivision 2 a of this subdivision.

c. The transmission of the useful beam through the primary protective barrier shall be limited such that the air kerma five cm from any accessible surface beyond the plane of the primary protective barrier does not exceed 0.88 microGy (0.1 mR exposure) for each activation of the tube.

3. Compliance with the requirements of subdivisions 1 and 2 c of this subsection for transmission shall be determined with the x-ray system operated at the minimum SID for which it is designed, at maximum rated peak tube potential, at the maximum rated product of x-ray tube current and exposure time (mAs) for the maximum rated peak tube potential, and by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm. The sensitive volume of the radiation measuring instrument shall not be positioned beyond the edge of the primary protective barrier along the chest wall side.

N. (Reserved.)

O. Beam limitation, except mammographic systems. The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam-limiting device meeting manufacturer's specifications and the requirements of subsection G of this section have been properly used or if evidence of collimation is shown on at least three sides or three corners of the film, for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge.

P. Radiation exposure control.

1. Exposure initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

2. Exposure indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

3. Operator protection, except veterinary systems.

a. Stationary systems. Stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area so that the operator may remain in that protected area during the entire exposure. For dental intraoral systems installed prior to September 20, 2006, if the x-ray control is not permanently mounted behind a protected barrier, then dosimetry is required by all operators of the system.

b. Mobile and portable systems. Mobile and portable x-ray systems that are:

(1) Used continuously for greater than one week in the same location, that is, a room or suite, shall meet the requirements of subdivision 3 a of this subsection;

(2) Used for less than one week at the same location shall be provided with either a protective barrier at least two meters (6.5 feet) high for operator protection during

exposures, or means shall be provided to allow the operator to be at least 2.7 meters (nine feet) from the tube housing assembly during the exposure.

4. Operator protection for veterinary systems. All stationary, mobile or portable x-ray systems used for veterinary work shall be provided with either a two meter (6.5 feet) high protective barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least 2.7 meters (nine feet) from the tube housing assembly during exposures.

Q. Tube stands for portable x-ray systems. A tube stand or other mechanical support shall be used for portable x-ray systems, so that the x-ray tube housing assembly need not be hand-held during exposures.

R. Surveys. Radiation safety and equipment performance surveys shall be performed annually on all x-ray machines covered by this section in order to assure compliance with the regulations, except that bone densitometers, hand-held units, and x-ray machines other than head CT or cone beam units used in the practice of podiatry, dentistry, or veterinary medicine shall be surveyed every three years. The surveys shall be performed by or under the direct supervision of a private or state inspector who is physically present at the facility during the inspection.

12VAC5-481-1630. (Repealed.)

12VAC5-481-1631. Intraoral Dental Radiographic Equipment.

In addition to the applicable provisions of 12VAC5-481-1591 , 12VAC5-481-1601 , and 12VAC5-481-1621 , the requirements of this section apply to x-ray equipment and associated facilities used for dental intraoral radiography. Requirements for extraoral dental radiographic systems are in 12VAC5-481-1621 .

1. Radiation exposure control. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action.

2. Exposure control location and operator protection.

a. Stationary x-ray systems shall be required to have the x-ray exposure control permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure; and

b. Mobile and portable x-ray systems that are:

(1) Used for greater than one week in the same location that is, a room or suite, shall meet the requirements of subdivision 2 a of this section.

(2) Used for less than one week in the same location shall be provided with either a protective barrier at least two meters (6.5 feet) high for operator protection, or means to allow the operator to be at least 2.7 meters (nine feet) from the tube housing assembly while making exposures.

3. kVp limitations. Dental x-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

4. Administrative controls.

a. Patient and film holding devices shall be used when the techniques permit.

b. The tube housing and the PID for a permanently mounted intraoral dental system shall not be hand-held during an exposure.

c. Dental fluoroscopy without image intensification shall not be used.

12VAC5-481-1640. (Repealed.)

12VAC5-481-1641. Computed Tomography Equipment.

A. (Reserved.)

B. Requirements for equipment.

1. Termination of exposure.

a. Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110% of its preset value through the use of either a backup timer or devices that monitor equipment function.

b. A visible signal shall indicate when the x-ray exposure has been terminated through the means required by subdivision 1 a of this subsection.

c. The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration.

2. Tomographic plane indication and alignment.

a. For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

b. For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

c. If a device using a light source is used to satisfy the requirements of subdivision 2 a or b of this subsection, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

3. Beam-on and shutter status indicators and control switches.

a. The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

b. Each emergency button or switch shall be clearly labeled as to its function.

4. Indication of CT conditions of operation. The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

5. Extraneous radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by subdivision 3 of 12VAC5-481-1601 .

6. Maximum surface CTDI identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

7. Additional requirements applicable to CT x-ray systems containing a gantry manufactured after September 3, 1985.

a. The total error in the indicated location of the tomographic plane or reference plane shall not exceed five mm.

b. If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

c. The deviation of indicated scan increment versus actual increment shall not exceed one millimeter with any mass from 0 to 100 kg resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 cm, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

d. Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

C. Facility design requirements.

1. Aural communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

2. Viewing systems.

a. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located

that the operator can observe the patient from the control panel.

b. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

D. Surveys, calibrations, spot checks, and operating procedures.

1. Surveys.

a. All CT x-ray systems installed after September 19, 2006, and those systems not previously surveyed shall have a survey made by, or under the direction of, a qualified medical physicist. In addition, such surveys shall be done after any change in the facility or equipment that might cause a significant increase in radiation hazard.

b. The registrant shall obtain a written report of the survey from the qualified medical physicist, and a copy of the report shall be made available to the agency upon request.

2. Radiation calibrations.

a. The calibration of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a qualified medical physicist who is physically present at the facility during such calibration.

b. The calibration of a CT x-ray system shall be performed (i) after initial installation and before use on human patients, (ii) annually or at intervals specified by a qualified medical physicist, and (iii) after any change or replacement of components that in the opinion of the qualified medical physicist could cause a change in the radiation output.

c. The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years.

d. CT dosimetry phantom shall be used in determining the radiation output of a CT x-ray system. Such phantom shall meet the following specifications and conditions of use:

(1) CT dosimetry phantom shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic cm. The phantom shall be at least 14 cm in length and shall have diameters of 32.0 cm for testing CT x-ray systems designed to image any section of the body and 16.0 cm for systems designed to image the head or for whole body scanners operated in the head scanning mode;

(2) CT dosimetry phantom shall provide means for the placement of a dosimeter along the axis of rotation and along a line parallel to the axis of rotation 1.0 cm from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided;

(3) Any effects on the doses measured due to the removal of phantom material to

accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom;and

(4) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

e. The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

f. Calibration shall meet the following requirements:

(1) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness;

(2) The CTDI along the two axes specified in subdivision 2 d (2) of this subsection shall be measured. For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 cm from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant; and

(3) The spot checks specified in subdivision 3 of this subsection shall be made.

g. Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the agency.

3. Spot checks.

a. The spot-check procedures shall be in writing and shall have been developed by a qualified medical physicist.

b. The spot-check procedures shall incorporate the use of a CT dosimetry phantom that has a capability of (i)providing an indication of contrast scale, noise, nominal tomographic section thickness, and the resolution capability of the system for low and high contrast objects; and (ii) measuring the mean CTN for water or other reference material.

c. All spot checks shall be included in the calibration required by subdivision 2 of this subsection and at time intervals and under system conditions specified by a qualified medical physicist.

d. Spot checks shall include acquisition of images obtained with the CT dosimetry phantom or phantoms using the same processing mode and CT conditions of operation as are used to perform calibrations required by subdivision 2 of this subsection.

e. The results of each spot check shall be maintained for two years.

4. Operating procedures.

a. The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation.

b. Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following:

(1) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;

(2) Instructions on the use of the CT dosimetry phantoms including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;

(3) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and

(4) A current technique chart available at the control panel that specifies for each routine examination the CT conditions of operation and the number of scans per examination.

c. If the calibration or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified medical physicist, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified medical physicist.

12VAC5-481-1650. (Repealed.)

12VAC5-481-1651. Mammography Requirements.

A. Only x-ray systems, pursuant to the Mammography Quality Standards Reauthorization Act of 1998 (Pub.L. 105-248) and 21 CFR Part 900, shall be used for screening and diagnostic mammography.

B. A facility performing mammography shall have a valid certificate issued by the U.S. Department of Health and Human Services, pursuant to the Mammography Quality Standards Reauthorization Act of 1998 and 21 CFR Part 900.

C. A facility performing mammography shall ensure that the additional mammography activities of processing the x-ray film, interpreting the image, and maintaining viewing conditions, wherever performed, meet all quality standards pursuant to the Mammography Quality Standards Reauthorization Act of 1998 and 21 CFR Part 900.

D. The operator of the mammography machine shall be certified by the American Registry of Radiologic Technologists (ARRT) and shall have had specialized training in mammography meeting the requirements set forth by the U.S. Food and Drug Administration under the Mammography Quality Standards Reauthorization Act of 1998.

E. When film developing is not available or the patient chooses not to wait, the patient shall be notified within two business days if another mammogram is necessary. This requirement does not imply or require that a diagnostic opinion be made at the time of the mammogram. The interpreting physician may require that the mammogram be retaken if, in the opinion of the physician, the study is of inadequate quality.

F. Agency inspectors may conduct unannounced inspections during normal business hours.

12VAC5-481-1653. Hand-Held Radiographic Unit.

In addition to the applicable provisions found elsewhere in this chapter, the following provisions apply to a hand-held radiographic unit.

1. A hand-held radiograph unit shall be:

   a. Certified by the manufacturer pursuant to 21 CFR Part 803, Medical Device Reporting of the Federal Food and Drug Administration Modernization Act of 1997; 21 USC Chapter 9, Subchapter V, Part C – Electronic Product Radiation Control (EPRC) (§ 360hh et seq.) of the Federal Food, Drug and Cosmetic Act; and 21 CFR 1020.30, Diagnostic x-ray systems and their major components.

   b. Registered with the agency in accordance with applicable parts of this chapter.

   c. Maintained and operated in accordance with the manufacturer's specifications.

2. For all uses:

   a. Operators of a hand-held radiographic unit shall be specifically trained to operate such equipment.

   b. When operating a hand-held radiographic unit, operators shall wear dosimetry unless otherwise authorized by the agency.

   c. A hand-held radiographic unit shall have the backscatter radiation shield in place to protect the operator during operation.

   d. The operator shall ensure there are no bystanders within a radius of at least six feet from the patient being examined with a hand-held radiograph unit.

   e. A hand-held radiographic unit shall not be used in hallways or waiting rooms.

12VAC5-481-1655. Bone Densitometry.

A. A bone densitometry system shall be:

1. Certified by the manufacturer pursuant to 21 CFR Part 803, Medical Device Reporting of the Federal Food and Drug Administration Modernization Act of 1997; 21 USC Chapter 9, Subchapter V, Part C – Electronic Product Radiation Control (EPRC) (§ 360hh et seq.) of the Federal Food, Drug and Cosmetic Act; and 21 CFR 1020.30, Diagnostic x-ray systems and their major components.

2. Registered with the agency in accordance with applicable parts of this chapter.

3. Maintained and operated in accordance with the manufacturer's specifications.

B. Equipment requirements. A system with stepless collimators shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond 2.0% of the SID.

C. Operators of a bone densitometry system shall meet one of the following:

1. Be certified by the American Registry of Radiologic Technologists (ARRT);

2. Be licensed by the Virginia Department of Health Professions, Board of Medicine as a radiologic technologist or a limited radiologic technologist for bone density operation;

3. Be licensed by the Virginia Department of Health Professions, Board of Medicine as a practitioner of the healing arts; or

4. Be in an accredited program for radiologic technology and under the supervision of an individual who meets one of the criteria listed in subdivision 1, 2, or 3 of this subsection.

D. During the operation of any bone densitometry system:

1. The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during the examination.

2. The operator shall advise the patient that the bone densitometry examination is a type of x-ray procedure.

E. The registrant shall keep maintenance records for bone densitometry systems as prescribed by subdivision A 3 of this section. These records shall be maintained for inspection by the agency.

F. Bone densitometry on human patients shall be conducted only:

1. Under a prescription of an individual licensed by the Virginia Department of Health Professions, Board of Medicine as a practitioner of the healing arts; or

2. Under a screening program approved by the agency.

12VAC5-481-1657. Quality Assurance Program.

All registrants of diagnostic x-ray imaging equipment may be required by the agency to establish and maintain a quality assurance program consisting of quality control assessments.

12VAC5-481-1660. Purpose and Scope.

Part VII. Use of Radionuclides in the Healing Arts

Article 1. Purpose and Scope

Part VII (12VAC5-481-1660 et seq.) of this chapter establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts

and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of Part VII (12VAC5-481-1660 et seq.) of this chapter are in addition to, and not in substitution for, others in these regulations. The requirements and provisions of these regulations apply to applicants and licensees subject to Part VII (12VAC5-481-1660 et seq.) of this chapter unless specifically exempted.

12VAC5-481-1670. General Requirements.

Article 2. General Information

A. Licensees may conduct research involving human research subjects only if it uses the radioactive materials specified on its license for the uses authorized on its license.

B. If the research is conducted, funded, supported, or regulated by another agency that has implemented a policy for protection of human subjects, the licensee shall, before conducting research:

1. Obtain review and approval of the research from an authorized review board; and

2. Obtain informed consent, in writing, from the human research subject.

C. If the research will not be conducted, funded, supported, or regulated by another agency that has implemented an appropriate protection policy, licensees shall, before conducting research, apply for and receive a specific license amendment to its medical use license. The amendment request shall include a written commitment that licensees will, before conducting research:

1. Obtain review and approval of the research from an authorized review board; and

2. Obtain informed consent, in writing, from the human research subject.

D. Nothing in this section relieves licensees from complying with other requirements of this part.

E. Nothing in this part relieves licensees from complying with applicable FDA, federal, and other state requirements governing radioactive drugs or devices.

F. When a requirement in this part differs from the requirement in an existing license condition, the requirement in this part shall govern.

G. Licensees shall continue to comply with any license condition that requires it to implement procedures required by 12VAC5-481-2043 and 12VAC5-481-2046 until there is a license amendment or renewal that modifies the license condition.

H. Each record required by this part shall be legible throughout the specified retention period. The record may be the original, a reproduced copy, or a microform if the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and

specifications shall include all pertinent information such as stamps, initials, and signatures. Licensees shall maintain adequate safeguards against tampering with and loss of records.

12VAC5-481-1680. Licensing and Exemptions.

A. A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer radioactive material for medical use only in accordance with a specific license issued by the agency, the NRC, or another agreement state, or as allowed in subsection B of this section.

B. A specific license is not needed for an individual who:

1. Receives, possesses, uses, or transfers radioactive material in accordance with this part under the supervision of an authorized user as provided in 12VAC5-481-1710 , unless prohibited by license condition; or

2. Prepares unsealed radioactive material for medical use in accordance with this part under the supervision of an authorized nuclear pharmacist or authorized user as provided in 12VAC5-481-1710 , unless prohibited by license condition.

C. An application shall be signed by the applicant's or licensee's management.

D. An application for a license for medical use of radioactive material as described in 12VAC5-481-1900 , 12VAC5-481-1920 , 12VAC5-481-1950 , 12VAC5-481-2010 , 12VAC5-481-2020 , 12VAC5-481-2040 B, and 12VAC5-481-2060 shall be made by:

1. Filing a completed and signed application for medical use; and

2. Submitting procedures required by 12VAC5-481-2043 and 12VAC5-481-2046 , as applicable.

E. A request for a license amendment or renewal shall be made by:

1. Submission of a license amendment may be completed by submitting in letter format including all necessary documentation;

2. Submission for a license renewal shall be completed by submitting a completed and signed renewal application for medical use; and

3. Submitting procedures required by 12VAC5-481-2043 and 12VAC5-481-2046 , as applicable.

F. In addition to the requirements in subsections D and E of this section, submittal of a license application or amendment for medical use of radioactive material as described in 12VAC5-481-2060 shall also include information regarding any radiation safety aspects of the medical use of the material that is not otherwise addressed in this part, including but not limited to, the following specific information:

1. Radiation safety precautions and instructions;

2. Training and experience of proposed users;

3. Methodology for measurement or dosages or doses to be administered to patients or

human research subjects;

4. Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

5. Any other information requested by the agency in its review of the application.

G. An applicant that satisfies the requirements specified in 12VAC5-481-470 may apply for a specific license of broad scope. Licensees possessing a Type A specific license of broad scope for medical use, issued under 12VAC5-481-470 , are exempt from:

1. The provisions of subsection E of this section regarding the need to file an amendment to the license for medical use of radioactive material, as described in 12VAC5-481-2060;

2. Additions to or changes in any authorized user, authorized nuclear pharmacist, or authorized medical physicist;

3. Additions to or changes in the areas of use at the addresses identified in the application or on the license;

4. The provisions of 12VAC5-481-1690 A;

5. The provisions of 12VAC5-481-1690 for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist;

6. The provisions of 12VAC5-481-1690 B 5;

7. The provisions of 12VAC5-481-1740 .

H. The agency shall issue a license for medical use of radioactive material if:

1. The applicant has filed the appropriate application form in accordance with the instructions in this subsection and subsections D, F, G, and I of this section;

2. The applicant has paid any applicable fee as provided in 12VAC5-490 ;

3. The agency finds the applicant equipped and committed to observe the safety standards established by the agency in this part for the protection of the public health and safety; and

4. The applicant meets the requirements of 12VAC5-481-450 .

I. The agency shall issue a license for mobile medical service if the applicant:

1. Meets the requirements of subsection H of this section and 12VAC5-481-1880; and

2. Assures that individuals or human research subjects to whom unsealed radioactive material or radiation from implants containing radioactive material will be administered may be released following treatment in accordance with 12VAC5-481-1870 .

J. The agency may, upon application of any interested person or upon its own initiative, grant exemptions from the regulations in this part that it determines are authorized by law and will not endanger life, property, or the common defense and security and are otherwise in the public interest.

12VAC5-481-1690. Notifications.

A. Licensees shall provide the agency the following information for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist:

1. A copy of (i) the board certification, (ii) the written attestation signed by a preceptor, and (iii) the NRC or another agreement state license;

2. The permit issued by a NRC master material licensee;

3. The permit issued by a broad scope licensee;

4. The permit issued by a NRC master material broad scope permittee; or

5. Documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC.

6. For individuals permitted to work within the 30-day time frame, the licensee shall also provide, as appropriate, verification of completion of:

a. Any additional case experience required in 12VAC5-481-1980 2 b (7) for an authorized user under 12VAC5-481-1950 ;

b. Any additional training required in 12VAC5-481-2040 A 4 for an authorized user under 12VAC5-481-2040 A; or

c. Any additional training required in 12VAC5-481-1760 A 3 for an authorized medical physicist.

B. A licensee shall notify the agency no later than 30 days after:

1. An authorized user, an authorized nuclear pharmacist, a radiation safety officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

2. The licensee permits an authorized user or an individual qualified to be a radiation safety officer, under 12VAC5-481-1750 and 12VAC5-481-1790 , to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer in accordance with 12VAC5-481-1700 C;

3. The licensee's mailing address changes;

4. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 12VAC5-481-500 B; or

5. The licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used in accordance with either 12VAC5-481-1900 or 12VAC5-481-1920 if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET

radionuclide/PET radioactive drug production area.

C. The licensee shall send the documents required in this section to the appropriate address identified in 12VAC5-481-150 .

12VAC5-481-1700. Authority and Responsibilities for the Radiation Protection Programs and Changes.

Article 3. General Administrative Requirements

A. In addition to the radiation protection program requirements of 12VAC5-481-630 , the licensee's management or designee shall approve, in writing:

1. Requests for a license application, renewal, or amendment before submittal to the agency;

2. Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or an authorized medical physicist; and

3. Radiation protection program changes that do not require a license amendment and are permitted under subsection F of this section.

B. The licensee's management shall appoint a radiation safety officer (RSO) who agrees, in writing, to be responsible for implementing the radiation protection program. This written document shall establish the authority, duties, and responsibilities of the RSO. Licensees, through the RSO, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. Licensees shall provide the RSO sufficient authority, organization freedom, time, resources, and management prerogative to:

1. Identify radiation safety problems;

2. Initiate, recommend, or provide corrective actions;

3. Stop unsafe operations; and

4. Verify implementation of corrective actions.

C. For up to 60 days each year, licensees may permit an authorized user or an individual qualified to be a RSO, under 12VAC5-481-1750 and 12VAC5-481-1790 , to function as a temporary radiation safety officer, as provided in subsection G if the licensee takes the actions required in subsections B, E, G, and H of this section and notifies the agency in accordance with 12VAC5-481-1690 B.

D. Licensees may simultaneously appoint more than one temporary RSO in accordance with subsection C of this section, if needed to ensure that the temporary RSO satisfies the requirements to be a RSO for each of the different types of uses of radioactive material permitted by the licensee.

E. Licensees that are authorized for two or more different types of uses of radioactive material under Articles 6, 7, and 9 of this part, or two or more types of units under 12VAC5-

481-2040 B, shall establish a Radiation Safety Committee (RSC) to oversee all uses of radioactive material permitted by the license. The RSC shall include an authorized user for each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor a RSO. The RSC may include other members the licensee considers appropriate.

F. A licensee may revise its radiation protection program without agency approval if:

1. The revision does not require a license amendment under 12VAC5-481-450 or 12VAC5-481-1680 ;

2. The revision is in compliance with this chapter and the license;

3. The revision has been reviewed and approved by the RSO and licensee management; and

4. The affected individuals are instructed on the revised program before the changes are implemented.

12VAC5-481-1710. Supervision.

A. Licensees that permit the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user, as allowed by 12VAC5-481-1680 B 1, shall:

1. In addition to the requirements in 12VAC5-481-2270 , instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations, and license conditions with respect to the use of radioactive material; and

2. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures established by the licensee, written directive procedures, regulations, and license conditions with respect to the medical use of radioactive material.

B. Licensees that permit the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by 12VAC5-481-1680 B 2, shall:

1. In addition to the requirements in 12VAC5-481-2270 , instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

2. Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, this chapter, and the license conditions.

C. Licensees that permit supervised activities under subsections A and B of this section are responsible for the acts and omissions of the supervised individual.

12VAC5-481-1720. Written Directives.

A. A written directive shall be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries (µCi) (1.11 megabecquerels (MBq)), any therapeutic dose of unsealed radioactive material, or any therapeutic dose of radiation from radioactive material.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive shall be documented as soon as possible in writing in the patient's record. A written directive shall be prepared within 48 hours of the oral directive.

B. The written directive shall contain the patient or human research subject's name and the following information:

1. For any administration of quantities greater than 30 µCi (1.11 MBq) of sodium iodide (I-131): the dosage;

2. For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide (I-131): the radioactive drug, dosage, and route of administration;

3. For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

4. For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

5. For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

6. For all other brachytherapy, including low, medium and pulsed dose rate remote afterloaders:

a. Before implantation: treatment site, the radionuclide, and dose; and

b. After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

C. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision shall be documented as soon as possible in the patient's record. A revised written directive shall be signed by the authorized user within 48 hours of the oral revision.

12VAC5-481-1730. Procedures for Administrations Requiring a Written

Directive.

For any administration requiring a written directive, licensees shall develop, implement, and maintain written directive procedures to provide high confidence that the patient's or human research subject's identity is verified before each administration and each administration is in accordance with the written directive. At a minimum, the procedures required by this section shall address the following items that are applicable to the licensee's use of radioactive material:

1. Verifying the identity of the patient or human research subject;

2. Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;

3. Checking both manual and computer-generated dose calculations; and

4. Verifying that all computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by 12VAC5-481-2040 B and 12VAC5-481-2060 .

12VAC5-481-1740. Suppliers for Sealed Sources or Devices for Medical Use.

For medical use, licensees may only use the following:

1. Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under this part or equivalent requirements of the NRC or another agreement state;

2. Sealed sources or devices non-commercially transferred from another medical use licensee;

3. Teletherapy sources manufactured and distributed in accordance with a license issued under Part III (12VAC5-481-380 et seq.) of this chapter or equivalent requirements of the NRC or another agreement state.

12VAC5-481-1750. Training for Radiation Safety Officer.

Except as provided in 12VAC5-481-1780 , licensees shall require an individual fulfilling the responsibilities of the radiation safety officer (RSO) as provided in 12VAC5-481-1700 to be an individual who:

1. Is certified by a specialty board who has been recognized by the NRC; or

2. Has completed a structured educational program consisting of provisions, as follows:

   a. 200 hours of classroom and laboratory training in the following areas:

   (1) Radiation physics and instrumentation;

   (2) Radiation protection;

   (3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Radiation biology; and

(5) Radiation dosimetry; and

b. One year of full-time radiation safety experience under the supervision of the individual identified as the RSO on an agency, NRC, or another agreement state license or permit issued by a master material licensee that authorizes similar types of uses of radioactive material involving the following:

(1) Shipping, receiving, and performing related radiation surveys;

(2) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(3) Securing and controlling radioactive material;

(4) Using administrative controls to avoid mistakes in the administration of radioactive material;

(5) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(6) Using emergency procedures to control radioactive material; and

(7) Disposing of radioactive material; or

3. Meets the following qualifications:

a. Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the NRC under 12VAC5-481-1760 A 1 and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as RSO and who meets the requirements in subdivisions 4 and 5 of this section; or

b. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has RSO responsibilities; and meets subdivisions 4 and 5 of this section; and

4. Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a RSO, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the types of use for which the licensee is seeking approval; and

5. Has obtained written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements in subdivisions 1, 2, or 3; and 4 of this section, and has achieved a level of radiation safety knowledge sufficient to function independently as a RSO for a medical use licensee.

12VAC5-481-1760. Training for an Authorized Medical Physicist.

Except as provided in 12VAC5-481-1780 , licensees shall require the authorized medical physicist (AMP) to be an individual who:

1. Is certified by a specialty board whose certification process has been recognized by the NRC, or

2. Meets the following requirements:

a. Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, health physics, other physical science, engineering, or applied mathematics from an accredited college or university or an equivalent training program approved by the agency, the NRC, or another agreement state and has completed one year of full-time training in medical physics and an additional year of full-time practical experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the types of use for which the individual is seeking authorization. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services and shall include:

(1) Performing sealed source leak tests and inventories;

(2) Performing decay corrections;

(3) Performing full calibration and periodic spot-checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(4) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

3. Has training for the types of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the types of use for which the individual is seeking authorization; and

4. Has obtained written attestation that the individual has satisfactorily completed the requirements of subdivisions 1 or 2; and 3 of this section; and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation shall be signed by a preceptor authorized medical physicist who meets the requirements in 12VAC5-481-1760 , 12VAC5-481-1780 , or equivalent requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

12VAC5-481-1770. Training for an Authorized Nuclear Pharmacist.

Except as provided in 12VAC5-481-1780 , licensees shall require the authorized nuclear

pharmacist (ANP) to be a pharmacist who:

1. Is certified by a specialty board whose certification process has been recognized by the NRC; or

2. Meets the following requirements:

a. Has completed 700 hours in a structured educational program consisting:

(1) 200 hours of classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Chemistry of byproduct material for medical use; and

(e) Radiation biology; and

(2) Supervised practical experience in a nuclear pharmacy involving:

(a) Shipping, receiving, and performing related radiation surveys;

(b) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha-emitting or beta-emitting radionuclides;

(c) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(d) Using administrative controls to avoid medical events in the administration of radioactive material; and

(e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

3. Has obtained written attestation, signed by a preceptor ANP, that the individual has satisfactorily completed the requirements in subdivision 1 or 2 of this section and has achieved a level of competency sufficient to function independently as an ANP.

12VAC5-481-1780. Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Nuclear Pharmacist, and Authorized User.

A. The following applies to individuals with experience as a radiation safety officer (RSO), teletherapy or medical physicist (AMP), or authorized nuclear pharmacist (ANP):

1. An individual identified as an RSO, AMP, or ANP on a specific license or a permit issued by the agency, the NRC, or another agreement state; broad scope licensee or master material license permit; or by a master material license permittee of broad scope that

authorizes medical use or the practice of nuclear pharmacy before October 24, 2002, need not comply with the training requirements of 12VAC5-481-1750 , 12VAC5-481-1760 , or 12VAC5-481-1770 , respectively.

2. An individual identified as an RSO, AMP, or ANP on a license or a permit issued by a the agency, NRC, or another agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope between October 24, 2002, and April 29, 2005, need not comply with the training requirements of 12VAC5-481-1750 , 12VAC5-481-1760 , or 12VAC5-481-1770 , respectively.

3. An RSO, AMP, or ANP, who used only accelerator-produced radioactive materials or discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of 12VAC5-481-1750 , 12VAC5-481-1760 , or 12VAC5-481-1770 , respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this subdivision, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of this part.

B. The following applies to experienced authorized users (AU):

1. Physicians, dentists, or podiatrists identified as AUs for the medical use of radioactive material on a license issued by the agency, the NRC, or another agreement state; a permit issued by an NRC master material licensee; a permit issued by an agency, NRC, or other agreement state broad scope licensee; or a permit issued by an NRC master material license broad scope permittee before October 24, 2002, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Articles 5 (12VAC5-481-1900 et seq.) through 9 (12VAC5-481-2040 et seq.) of this part.

2. Physicians, dentists, or podiatrists identified as AUs for the medical use of radioactive material on a license issued by the agency, the NRC, or another agreement state; a permit issued by an NRC master material licensee; a permit issued by an agency, NRC, or other agreement state broad scope licensee; or a permit issued by an NRC master material license broad scope permittee who perform only those medical uses for which they were authorized between October 24, 2002, and April 29, 2005, need not comply with the training requirements of Articles 5 (12VAC5-481-1900 et seq.) through 9 (12VAC5-481-2040 et seq.) of this part.

3. Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials or discrete sources of radium-226, or both, for medical uses performed at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of Articles 5 (12VAC5-481-1900 et seq.)

through 9 (12VAC5-481-2040 et seq.) of this part when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both for medical uses at the locations and time period identified in this subdivision, qualifies as an AU for those materials and uses performed before these dates for purposes of this chapter.

C. Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on NRC licenses for the same uses for which these individuals are authorized.

12VAC5-481-1790. Recentness of Training.

The training and experience specified in this article and Articles 5 (12VAC5-481-1900 et seq.), 6 (12VAC5-481-1950 et seq.), 7 (12VAC5-481-2010 et seq.), 8 (12VAC5-481-2020 et seq.), and 9 (12VAC5-481-2040 et seq.) of this part shall have been obtained within the seven years preceding the date of the application or the individual shall have had related continuing education and experience since the required training and experience was completed.

12VAC5-481-1800. Possession, Use, and Calibration of Instruments Used to Measure the Activity of Unsealed Radioactive Material.

Article 4. General Technical Requirements

A. For direct measurements performed in accordance with 12VAC5-481-1820 , licensees shall possess and use instrumentation to measure the activity of unsealed radioactive material before it is administered to each patient or human research subject.

B. Licensees shall test the instrumentation required by subsection A of this section in accordance with nationally recognized standards or the manufacturer's instructions.

12VAC5-481-1810. (Repealed.)

12VAC5-481-1820. Determination of Dosages of Unsealed Radioactive Material for Medical Use.

A. Licensees shall determine and record the activity of each dosage before medical use.

B. For a unit dosage, this determination shall be made by:

1. Direct measurement of the radioactivity; or

2. A decay correction based on activity or activity concentration determined by:

   a. A manufacturer or preparer licensed under 12VAC5-481-480 I or equivalent NRC or other agreement state requirements;

   b. An agency, NRC, or another agreement state licensee for use in research in accordance with Radioactive Drug Research Committee-approved protocol or Investigational New Drug (IND) protocol accepted by FDA; or

c. A PET radioactive drug producer licensed under 12VAC5-481-440 H or equivalent NRC or other agreement state requirements.

C. For other than unit dosages, this determination shall be made by:

1. Direct measurement of radioactivity;

2. Combination of measurement of radioactivity and mathematical calculations; or

3. Combination of volumetric measurements and mathematical calculations, based on the measurement made by:

a. A manufacturer or preparer licensed under 12VAC5-481-480 I or equivalent NRC or other agreement state requirements; or

b. A PET radioactive drug producer licensed under 12VAC5-481-440 H or equivalent NRC or other agreement state requirements.

D. Unless otherwise directed by the authorized user, licensees may not use a dosage if the dosage does not fall within the prescribed dosage range or the dosage differs from the prescribed dosage by more than 20%.

12VAC5-481-1830. Authorization for Calibration, Transmission, and Reference Sources.

Any person authorized by 12VAC5-481-1680 for medical use of radioactive material may receive, possess, and use any of the following radioactive material for check, calibration, transmission, and reference use:

1. Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under 12VAC5-481-480 or equivalent NRC or other agreement state regulations.

2. Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under 12VAC5-481-480 or equivalent NRC or other agreement state regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

3. Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).

4. Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 µCi) or 1000 times the quantities in 12VAC5-481-3730 .

5. Technetium-99m in amounts as needed.

12VAC5-481-1840. Requirements for Possession of Sealed Sources and Brachytherapy Sources.

A. Licensees in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

B. Licensees in possession of a sealed source shall:

1. Test the source for leakage before its first use unless the licensee has a certificate from the supplied indicating that the source was tested within six months before transfer to the licensee; and

2. Test the source for leakage at intervals not to exceed six months or at other intervals approved by the NRC or another agreement state in the Sealed Source and Device Registry.

C. To satisfy the leak test requirements of this section, licensees shall measure the sample so that the leak test can detect the presence of 0.005 µCi (185 Bq) of radioactive material in the sample.

D. If the leak test reveals the presence of 0.005 µCi (185 Bq) or more of removable contamination, the licensee shall:

1. Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in Parts III (12VAC5-481-380 et seq.) and IV (12VAC5-481-600 et seq.) of this chapter; and

2. File a report within five days of the leak test in accordance with 12VAC5-481-2080 C.

E. Licensees need not perform a leak test on the following sources:

1. Containing only radioactive material with a half-life of less than 30 days;

2. Containing only radioactive material as a gas;

3. Containing 100 µCi (3.7 MBq) or less of beta or gamma-emitting material;

4. Containing 10 µCi (0.37 MBq) or less of alpha-emitting material;

4. Seeds of iridium-192 encased in nylon ribbon; and

5. Sources stored and not being used. However, the licensee shall test each such source for leakage before any use or transfer unless it has been leak tested within six months before the date of use or transfer.

F. Licensees in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession.

12VAC5-481-1850. Labeling of Vials and Syringes.

Each syringe and vial that contains unsealed radioactive material shall be labeled to identify the radioactive drug. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

12VAC5-481-1860. Surveys of Ambient Radiation Exposure Rate.

A. In addition to the surveys required by Part IV (12VAC5-481-600 et seq.) of this chapter, licensees shall survey with a radiation detection survey instrument at the end of each day of use. Licensees shall survey all areas where unsealed radioactive material requiring a written directive was prepared for use or administered.

B. Licensees do not need to perform the surveys required by subsection A of this section in an area where patients or human research subjects are confined when they cannot be released under 12VAC5-481-1870 .

12VAC5-481-1870. Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material.

A. Licensees may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 500 mrem (5 mSv).

B. Licensees shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonable achievable if the total effective dose equivalent to any other individual is likely to exceed 100 mrem (1 mSv). If the total effective dose equivalent to a nursing infant or child could exceed 100 mrem (1 mSv), assuming there were no interruption of breast-feeding, the instructions shall also include:

1. Guidance on the interruption or discontinuation of breast-feeding; and

2. Information on the potential consequences, if any, on failure to follow guidance.

12VAC5-481-1880. Provision of Mobile Medical Service.

A. The mobile medical service shall be licensed if the service receives, uses, or possesses radioactive material. The client of the mobile medical service shall be licensed if the client receives or possesses radioactive material to be used by a mobile medical service.

B. Licensees providing mobile medical service shall:

1. Obtain a letter signed by the management of each client for whom services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

2. Inform the client's management who is on site at each client's address of use at the time that radioactive material is being administered;

3. Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this subdivision shall include a constancy check;

4. Check survey instruments for proper operation with a dedicated check source before use at each client's address; and

5. Before leaving a client's address, survey all areas of use for dose rate and removable contamination to ensure compliance with the requirements in Part IV (12VAC5-481-600 et seq.) of this chapter.

C. A mobile medical service may not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.

12VAC5-481-1890. Decay-In-Storage.

Licensees may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if it:

1. Monitors material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

2. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

12VAC5-481-1900. Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive Is Not Required.

Article 5. Unsealed Byproduct Material – Written Directive Not Required

Except for quantities that require a written directive under 12VAC5-481-1720 , licensees may use any unsealed radioactive material prepared for medical use for uptake, dilution, or excretion studies that is:

1. Obtained from a manufacturer or preparer licensed under 12VAC5-481-480 I or equivalent NRC or other agreement state regulations or a PET radioactive drug producer licensed under 12VAC5-481-440 H or equivalent NRC or other agreement state requirements;

2. Excluding PET radionuclides, prepared by (i) an ANP; (ii) a physician who is an AU and who meets the requirements specified in 12VAC5-481-1940 or 12VAC5-481-1980 and 12VAC5-481-1940 3 a 1; or (iii) an individual under supervision, as specified in 12VAC5-481-1710;

3. Obtained from and prepared by an agency, NRC, or another agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigation New Drug (IND) protocol accepted by FDA; or

4. Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigation New Drug (IND) protocol accepted by FDA for use in research.

12VAC5-481-1910. Training for Uptake, Dilution, and Excretion Studies.

Except as provided in 12VAC5-481-1780 , licensees shall require an authorized user of unsealed radioactive material for the uses authorized under 12VAC5-481-1900 to be a physician:

1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC and who meets the requirements in subdivision 3 b of this section;

2. Who is an authorized user under 12VAC5-481-1940 , 12VAC5-481-1980 , or equivalent NRC or other agreement state requirements; or

3. Who has:

a. Completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience shall include the following:

(1) Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Chemistry of radioactive material for medical use; and

(e) Radiation biology; and

(2) Work experience under the supervision of an authorized user who meets the requirements in this section, 12VAC5-481-1780 , 12VAC5-481-1940 , 12VAC5-481-1980 , or equivalent NRC or other agreement state requirements, involving:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(c) Calculating, measuring, and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(f) Administering dosages of radioactive drugs to patients or human research subjects; and

b. Obtained written attestation, signed by a preceptor authorized user who meets the requirements in this section, 12VAC5-481-1780 , 12VAC5-481-1940 , or 12VAC5-481-1980 , or equivalent NRC or other agreement state requirements, that the individual has satisfactorily completed the requirements in subdivisions 1 a or 3 a of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 12VAC5-481-1900 .

12VAC5-481-1920. Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive Is Not Required.

Except for quantities that require a written directive under 12VAC5-481-1720 , licensees may use any unsealed radioactive material prepared for medical use for imaging and localization studies that is:

1. Obtained from a manufacturer or preparer licensed under 12VAC5-481-480 I or equivalent NRC or other agreement state requirements or a PET radioactive drug producer licensed under 12VAC5-481-440 H or equivalent NRC or other agreement state requirements;

2. Excluding production of PET radionuclides, prepared by an ANP; a physician who is an authorized user (AU) and who meets the requirements specified in 12VAC5-481-1940 , or 12VAC5-481-1980 and 12VAC5-481-1940 3 a (1) (g); or an individual under the supervision, as specified in 12VAC5-481-1710 , of an ANP or a physician who is an AU;

3. Obtained from and prepared by an agency, NRC, or another agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

4. Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA.

12VAC5-481-1930. Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.

A. Licensees may not administer to humans a radiopharmaceutical that contains:

1. More than 0.15 µCi of molybdenum-99 per mCi of technetium-99m (0.15 kBq of molybdenum-99 per MBq of technetium-99m); or

2. More than 0.02 µCi of strontium-82 per mCi of rubidium-82 chloride (0.02 kBq of strontium-82 per MBq of rubidium-82 chloride injection) or more than 0.2 µCi of strontium-85 per mCi of rubidium-82 (0.2 kBq of strontium-85 per MBq of rubidium-82 chloride injection).

B. To demonstrate compliance with subsection A of this section, the licensee preparing the radioactive drug from the radionuclide generator shall:

1. Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator;

2. Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems, not to exceed before the first patient use of the day for a strontium/rubidium-82 generator.

12VAC5-481-1940. Training for Imaging and Localization Studies.

Except as provided in 12VAC5-481-1780 , licensees shall require an authorized user (AU) of unsealed radioactive material for the uses authorized under 12VAC5-481-1920 to be a physician:

1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC and who meets the requirements in subdivision 3 b of this section;

2. Who is an AU under 12VAC5-481-1980 and meets the requirements in subdivision 3 a (2) (g) of this section, or equivalent NRC or other agreement state requirements; or

3. Who has:

a. Completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience shall include at a minimum:

(1) Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Chemistry of radioactive material for medical use; and

(e) Radiation biology; and

(2) Work experience, under the supervision of an authorized user who meets the requirements in this section, 12VAC5-481-1780 , or 12VAC5-481-1980 and subdivision 3 a (2) (g) of this section, or equivalent NRC or other agreement state requirements, involving:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(c) Calculating, measuring, and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(e) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(f) Administering dosages of radioactive drugs to patients or human research subjects; and

(g) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

b. Obtained written attestation, signed by a preceptor authorized user who meets the requirements in this section, 12VAC5-481-1780 , or 12VAC5-481-1980 and subdivision 3 a (2) (g), or equivalent NRC or other agreement state requirements, that the individual has satisfactorily completed the requirements in subdivisions 1 a or 3 a of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 12VAC5-481-1900 and 12VAC5-481-1920 .

12VAC5-481-1950. Use of Unsealed Radioactive Material for Which a Written Directive Is Required.

Article 6. Unsealed Byproduct Material - Written Directive Required

Licensees may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is:

1. Obtained from a manufacturer or preparer licensed under 12VAC5-481-480 I or equivalent NRC or other agreement state requirements or a PET radioactive drug producer licensed under 12VAC5-481-440 H or equivalent NRC or another agreement state requirements;

2. Excluding production of PET radionuclides, prepared by an ANP; a physician who is an authorized user (AU) and who meets the requirements specified in 12VAC5-481-1940 or 12VAC5-481-1980; or an individual under the supervision, as specified in 12VAC5-481-1710 , of an ANP or the physician who is an AU;

3. Obtained from and prepared by an agency, NRC, or another agreement state licensee for use in research in accordance with an investigational new drug (IND) protocol accepted by U.S. Food and Drug Administration (FDA); or

4. Prepared by the licensee for use in research in accordance with an IND protocol accepted by FDA.

12VAC5-481-1960. Safety Instruction.

In addition to the requirements of 12VAC5-481-2270 , licensees shall provide radiation safety instruction initially and at least annually to personnel caring for patients or human research subjects who cannot be released under 12VAC5-481-1870 . To satisfy this requirement, the

instruction shall be commensurate with the duties of the personnel and include:

1. Patient or human research subject control;

2. Visitor control, including:

a. Routine visitation to hospitalized individuals in accordance with 12VAC5-481-720 A 1; and

b. Visitation authorized in accordance with 12VAC5-481-720 C;

3. Contamination control;

4. Waste control; and

5. Notification of the RSO, or his designee, and an authorized user if the patient or human research subject has a medical emergency or dies.

12VAC5-481-1970. Safety Precautions.

A. For each patient or human research subject who cannot be released under 12VAC5-481-1870 , licensees shall:

1. Quarter the patient or the human research subject either in:

a. A private room with a private sanitary facility; or

b. A room, with a private sanitary facility, with another individual who also has received therapy with unsealed byproduct material and who also cannot be released under 12VAC5-481-1870;

2. Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign;

3. Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room; and

4. Either monitor material and items removed from the patient's or human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding or handle the material and items as radioactive waste.

B. Licensees shall notify the RSO, or his designee, and an AU as soon as possible if the patient or human research subject has a medical emergency or dies.

12VAC5-481-1980. Training for Use of Unsealed Radioactive Material for Which a Written Directive Is Required.

Except as provided in 12VAC5-481-1780 , licensees shall require an authorized user (AU) of unsealed radioactive material for the uses authorized under 12VAC5-481-1950 to be a physician:

1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC; or

2. Who has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience shall include:

a. Classroom and laboratory training in the following areas:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Chemistry of radioactive material for medical use; and

(5) Radiation biology; and

b. Work experience under the supervision of an AU who meets the requirements in this section, 12VAC5-481-1780 , or equivalent NRC or another agreement state requirements. A supervising AU, who meets the requirements of this subdivision 2 shall also have experience in administering dosages in the same dosage category or categories (i.e., subdivision 2 b (7) of this section) as the individual requesting authorized user status. The work experience shall involve:

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(2) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(3) Calculating, measuring, and safely preparing patient or human research subject dosages;

(4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

(6) (Reserved.)

(7) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each categories for which the individual is requesting authorized user status. These categories are oral administration of less than or equal to 33 mCi (1.22 GBq) of sodium iodide I-131, for which a written directive is required; oral administration of greater than 33 mCi (1.22 GBq) of sodium iodide I-131; parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; or parenteral

administration of any other radionuclide, for which a written directive is required.

3. Who has obtained written attestation that the individual has satisfactorily completed the requirements in either subdivisions 1 and 2 b (7) of this section or subdivision 2 of this section and has achieved a level of competency sufficient to function independently as an AU for the medical uses authorized under 12VAC5-481-1950 . The written attestation shall be signed by a preceptor AU who meets the requirements in this section, 12VAC5-481-1780 , or equivalent NRC or other agreement state requirements. The preceptor AU, who meets the requirements in subdivision 2 of this section shall have experience in administering dosages in the same dosage category or categories (i.e., subdivision 2 b (7) of this section) as the individual requesting authorized user status.

12VAC5-481-1990. Training for the Oral Administration of Sodium Iodide (I-131) Requiring a Written Directive in Quantities Less Than or Equal to 33 Mci (1.22 Gbq).

Except as provided in 12VAC5-481-1780 , licensees shall require an authorized user (AU) for the oral administration of sodium iodide (I-131) requiring a written directive in quantities less than or equal to 33 mCi (1.22 GBq) to be a physician:

1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC; or

2. Who is an AU under 12VAC5-481-1980 for uses listed in subdivision 2 b (7) of 12VAC5-481-1980 , 12VAC5-481-2000 , or equivalent NRC or other agreement state requirements; or

3. Who has:

a. Completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide (I-131) for procedures requiring a written directive. The training shall include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Chemistry of byproduct material for medical use; and

(5) Radiation biology; and

b. Work experience under the supervision of an AU who meets the requirements in this section, 12VAC5-481-1780 , 12VAC5-481-1980 , 12VAC5-481-2000 , or equivalent NRC or another agreement state requirements. A supervising AU who meets the requirements in subdivision 2 of 12VAC5-481-1980 shall also have experience in administering dosages as specified in subdivision 2 b (7) of 12VAC5-481-1980 . The work experience shall involve:

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(3) Calculating, measuring, and safely preparing patient or human research subject dosages;

(4) Using administrative controls to prevent a medical event involving the use of byproduct material;

(5) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(6) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of less than or equal to 33 mCi (1.22 GBq) of sodium iodide (I-131); and

4. Obtained written attestation that the individual has satisfactorily completed the requirements in subdivisions 1 and 3 b of this section or subdivision 3 of this section and has achieved a level of competency sufficient to function independently as an AU for medical uses authorized under 12VAC5-481-1950 . The written attestation shall be signed by a preceptor AU who meets the requirements in this section, 12VAC5-481-1780 , 12VAC5-481-1980 , 12VAC5-481-2000 , or equivalent NRC or other agreement state requirements. A preceptor AU who meets the requirement in subdivision 2 of 12VAC5-481-1980 shall also have experience in administering dosages as specified in subdivision 2 b (7) of 12VAC5-481-1980 .

12VAC5-481-2000. Training for the Oral Administration of Sodium Iodide (I-131) Requiring a Written Directive in Quantities Greater Than 33 Mci (1.22 Gbq).

Except as provided in 12VAC5-481-1780 , licensees shall require an authorized user (AU) for the oral administration of sodium iodide (I-131) requiring a written directive in quantities greater than 33 mCi (1.22 GBq) to be a physician:

1. Who is certified by a medical specialty board whose certification has been recognized by the NRC;

2. Who is an AU under 12VAC5-481-1980 for uses listed in subdivision 2 b (7) of 12VAC5-481-1980 or equivalent NRC or other agreement state requirements; or

3. Who has:

a. Completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide (I-131) for procedures requiring a written directive. The training shall include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Chemistry of radioactive material for medical use; and

(5) Radiation biology; and

b. Work experience, under the supervision of an AU who meets the requirements in this section, 12VAC5-481-1780 , 12VAC5-481-1980 , 12VAC5-481-1990 , or equivalent NRC or other agreement state requirements. A supervising AU who meets the requirements in subdivision 2 of 12VAC5-481-1980 shall also have experience in administering dosages as specified in subdivision 2 b (7) of 12VAC5-481-1980 . The work experience shall involve:

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(3) Calculating, measuring, and safely preparing patient or human research subject dosages;

(4) Using administrative controls to prevent a medical event involving the use of radioactive material;

(5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(6) Administering dosages to patients or human research subjects that includes at least three cases involving the oral administration of greater than 33 mCi (1.22 GBq) of sodium iodide (I-131); and

c. Obtained written attestation that the individual has satisfactorily completed the requirements in subdivisions 1 and 3 b of this section or subdivision 3 of this section and has achieved a level of competency sufficient to function independently as an AU for medical uses authorized under 12VAC5-481-1950 . The written attestation shall be signed by a preceptor AU who meets the requirements in this section, 12VAC5-481-1780 , 12VAC5-481-1980 , 12VAC5-481-1990 , or equivalent NRC or other agreement state requirements. A preceptor AU who meets the requirements in subdivision 2 of 12VAC5-481-1980 shall also have experience in administering dosages as specified in subdivision 2 b (7) of 12VAC5-481-1980 .

12VAC5-481-2001. Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive.

Except as provided in 12VAC5-481-1780 , licensees shall require an authorized user (AU) for the parenteral administration requiring a written directive to be a physician:

1. Who is an AU under 12VAC5-481-1980 for uses listed in subdivision 2 b (7) of 12VAC5-481-1980 or equivalent NRC or other agreement state requirements;

2. Who is an AU under 12VAC5-481-2010 , 12VAC5-481-2040 , or equivalent NRC or other agreement state requirements and who meets the requirements in subdivision 4 of this section; or

3. Who is certified by a medical specialty board whose certification process has been recognized by the NRC; or

4. Who has:

a. Completed 80 hours of classroom and laboratory training applicable to parenteral administrations for which a written directive is required of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required. The training shall include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Chemistry of radioactive material for medical use; and

(5) Radiation biology; and

b. Work experience under the supervision of an AU who meets the requirements in this section, 12VAC5-481-1780 , 12VAC5-481-1980 , or equivalent NRC or other agreement state requirements in the parenteral administration for which a written directive is required of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required. A supervising AU who meets the requirements in 12VAC5-481-1980 shall have experience in administering dosages as specified in subdivision 2 b (7) of 12VAC5-481-1980 . The work experience shall involve:

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(3) Calculating, measuring, and safely preparing patient or human research subject dosages;

(4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(6) Administering dosages to patients or human research subjects that include at least three cases involving the parenteral administration for which a written directive is required of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or at least three cases involving the parenteral administration of any other radionuclide for which a written directive is required; and

5. Obtained a written attestation that the individual has satisfactorily completed the requirements in subdivision 2 or 3; and subdivision 4 b of this section or subdivision 4 of this section, and has achieved a level of competency sufficient to function independently as an AU for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation shall be signed by a preceptor AU who meets the requirements in this section, 12VAC5-481-1780 , 12VAC5-481-1980 , or equivalent NRC or other agreement state requirements. A preceptor AU who meets the requirements in 12VAC5-481-1980 shall have experience in administering dosages as specified in subdivision 2 b (7) of 12VAC5-481-1980 .

12VAC5-481-2010. Use of Sources for Manual Brachytherapy.

Article 7. Manual Brachytherapy

Licensees shall use only brachytherapy sources for therapeutic medical uses:

1. As approved in the Sealed Source and Device Registry; or

2. In research in accordance with an active Investigational Device Exemption application accepted by the U.S. Food and Drug Administration provided the requirements of 12VAC5-481-1740 are met.

12VAC5-481-2011. Surveys After Source Implant and Removal.

A. Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.

B. Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

C. A licensee shall retain a record of the surveys required by subsections A and B of this section in accordance with 12VAC5-481-2070 O.

12VAC5-481-2012. Brachytherapy Sources Accountability.

A. Licensees shall maintain accountability at all times for all brachytherapy sources in storage or use.

B. As soon as possible after removing sources from a patient or a human research subject, licensees shall return brachytherapy sources to a secure storage area.

12VAC5-481-2013. Safety Instruction.

A. In addition to the requirements of 12VAC5-481-2270 , licensees shall provide radiation safety instruction initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under 12VAC5-481-1870 .

B. To satisfy this requirement, the instruction shall be commensurate with the duties of the personnel and include:

1. Size and appearance of the brachytherapy sources;

2. Safe handling and shielding instructions;

3. Patient or human research subject control;

4. Visitor control, including both:

a. Routine visitation of hospitalized individuals in accordance with 12VAC5-481-720 A 1; and

b. Visitation authorized in accordance with 12VAC5-481-720 C; and

5. Notification of the RSO, or his designee, and an AU if the patient or the human research subject has a medical emergency or dies. The licensee shall also notify the agency if it is possible that any individual could receive exposures in excess of regulatory limits as a result of the deceased's body.

12VAC5-481-2014. Safety Precautions.

A. For each patient or human research subject who is receiving brachytherapy and cannot be released under 12VAC5-481-1870 , licensees shall:

1. Not quarter the patient or human research subject in the same room as an individual who is not receiving brachytherapy;

2. Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and

3. Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

B. Licensees shall have applicable emergency response equipment available near each treatment room to respond to a source that becomes:

1. Dislodged from the patient; and

2. Lodged within the patient following removal of the source applicators.

C. Licensees shall notify the RSO, or his designee, and an AU as soon as possible if the patient or human research subject has a medical emergency or dies.

12VAC5-481-2015. Calibration Measurements of Brachytherapy Sources.

A. Before the first medical use of a brachytherapy source, licensees shall have:

1. Determined the source output or activity using a dosimetry system that meets the requirements of 12VAC5-481-2044 ;

2. Determined source positioning accuracy with applicators; and

3. Used published protocols currently accepted by nationally recognized bodies to meet the requirements of subdivision 1 and 2 of this subsection.

B. Instead of a licensee making its own measurements as required in subsection A of this section, the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with subsection A of this section.

C. A licensee shall mathematically correct the outputs or activities determined in subsection A of this section for physical decay at intervals consistent with 1.0% physical decay.

12VAC5-481-2016. Decay of Strontium-90 Sources for Ophthalmic Treatments.

Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay shall be based on the activity determined under 12VAC5-481-2015 .

12VAC5-481-2017. Therapy-Related Computer Systems.

Licensees shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of:

1. The source-specific input parameters required by the dose calculation algorithm;

2. The accuracy of dose, dwell time, and treatment time calculations at representative points;

3. The accuracy of isodose plots and graphic displays; and

4. The accuracy of the software used to determine sealed source positions from radiographic images.

12VAC5-481-2018. Training for Use of Manual Brachytherapy Sources.

Except as provided in 12VAC5-481-1780 , licensees shall require an authorized user of a manual brachytherapy source for uses authorized under 12VAC5-481-2010 to be a physician:

1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC; or

2. Who has:

a. Completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

(1) 200 hours of classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and

(d) Radiation biology; and

(2) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this subsection, 12VAC5-481-1780 , or equivalent NRC or another agreement state requirements at a medical institution, involving:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Checking survey meters for proper operation;

(c) Preparing, implanting, and removing brachytherapy sources;

(d) Maintaining running inventories of material on hand;

(e) Using administrative controls to prevent a medical event involving the use of radioactive material;

(f) Using emergency procedures to control radioactive material; and

b. Completed three years of supervised clinical experience in radiation oncology, under an AU who meets the requirements in this section, 12VAC5-481-1780 , or equivalent NRC or another agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subdivision 2 a (2) of this section.

3. Who has obtained written attestation, signed by a preceptor AU who meets the requirements in this section, 12VAC5-481-1780 , or equivalent NRC or other agreement state requirements, that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU of manual brachytherapy sources for the medical uses authorized in 12VAC5-481-2010 .

12VAC5-481-2019. Training for Ophthalmic Use of Strontium-90.

Except as provided in 12VAC5-481-1780 , licensees shall require the AU of strontium-90 for

ophthalmic radiotherapy to be a physician:

1. Who is an authorized user (AU) under 12VAC5-481-2018 or equivalent NRC or other agreement state requirements; or

2. Who has:

a. Completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training shall include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

b. Clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training shall involve:

(1) Examination of each individual to be treated;

(2) Calculation of the dose to be administered;

(3) Administration of the dose; and

(4) Follow up and review of each individual's case history; and

c. Obtained written attestation, signed by a preceptor AU who meets the requirements in 12VAC5-481-1780 , 12VAC5-481-2018 , this section, or equivalent NRC or other agreement state requirements, that the individual has satisfactorily completed the requirements in this subdivision 2 and has achieved a level of competency sufficient to function independently as an AU of strontium-90 for ophthalmic use.

12VAC5-481-2020. Use of Sealed Sources for Diagnosis.

Article 8. Sealed Sources for Diagnosis

Licensees shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

12VAC5-481-2030. Training for Use of Sealed Sources for Diagnosis.

Except as provided by 12VAC5-481-1780 , licensees shall require the authorized user of a diagnostic sealed source for use in a device authorized under 12VAC5-481-2020 to be a physician, dentist, or podiatrist who:

1. Is certified by a specialty board that has been recognized by the NRC; or

2. Has completed eight hours of classroom and laboratory training in basic radionuclide

handling techniques specifically applicable to the use of the device. The training shall include:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and

d. Radiation biology; and

3. Has completed training in the use of the device for the uses requested.

12VAC5-481-2040. Training Requirements and Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.

Article 9. Photon Emitting Remote Afterloader Units, Teletherapy Units, and Stereotactic Radiosurgery Units

A. Except as provided in 12VAC5-481-1780 , licensees shall require an authorized user (AU) of a sealed source in remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units to be a physician:

1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC; or

2. Who has:

a. Completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

(1) 200 hours of classroom and laboratory training in the following areas: radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; and radiation biology; and

(2) 500 hours of work experience, under the supervision of an AU who meets the requirements in this section, 12VAC5-481-1780 , or equivalent NRC or another agreement state requirements at a medical institution, involving: reviewing full calibration measurements and periodic spot-checks; preparing treatment plans and calculating treatment doses and times; using administrative controls to prevent a medical event involving the use of radioactive material; implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console; checking and using survey meters; and selecting the proper dose and knowing how it is to be administered; and

b. Completed three years of supervised clinical experience in radiation therapy under an AU who meets the requirements in this section, 12VAC5-481-1780 , or equivalent NRC or another agreement state requirements as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation

Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by this subdivision.

3. Who has obtained written attestation that the individual has satisfactorily completed the requirements in (i) subdivision 1 or 2 of this subsection and (ii) subdivisions 3 and 4 of this subsection and has achieved a level of competency sufficient to function independently as an AU of each type of therapeutic medical unit for which the individual is requesting AU status. The written attestation shall be signed by a preceptor AU who meets the requirements in this subsection, 12VAC5-481-1780 , or equivalent NRC or another agreement state requirements for an AU for each type of therapeutic medical unit for which the individual is requesting AU status.

4. Who has received training in device operation, safety procedures, and clinical use for the types of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an AU or authorized medical physicist, as appropriate, who is authorized for the types of use for which the individual is seeking authorization.

B. Licensees shall use sealed sources in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

1. As approved in the Sealed Source and Device Registry; or

2. In research in accordance with an active Investigational Device Exemption application accepted by the U.S. Food and Drug Administration provided the requirements of 12VAC5-481-1740 are met.

12VAC5-481-2041. Surveys Required.

A. Radiation surveys.

1. In addition to the survey requirements in 12VAC5-481-750 , licensees shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

2. The licensee shall make the survey required by subdivision 1 of this subsection at installation of a new source and following repairs to the source shielding, the source driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the unit or the source.

B. Patient surveys. Before releasing a patient or human research subject from licensee control, a licensee shall survey the patient or human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source has been removed from the patient or human research subject and returned to the safe shielded position.

12VAC5-481-2042. Installation, Maintenance, Adjustment, and Repair.

A. Only a person specifically licensed by the agency, the NRC, or another agreement state shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source shielding, the source driving unit, or other electronic or mechanical components that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the unit or the source.

B. Except for low dose-rate remove afterloader unit, only a person specifically licensed by the agency, the NRC, or another agreement state shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

C. For a low dose-rate remote afterloader unit, only a person specifically licensed by the agency, the NRC, or another agreement state or an authorized medical physicist shall install, replace, relocate, or remove a sealed source contained in the unit.

12VAC5-481-2043. Safety Procedures and Instructions, and Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

A. Safety procedures and instructions.

1. Licensees shall:

   a. Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

   b. Permit only individuals approved by the authorized user (AU), the authorized medical physicist (AMP), or the RSO to be present in the treatment room during treatment with sources;

   c. Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

   d. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source in the shielded position, or remove the patient or human research subject from the radiation field with controls from the outside the treatment room. These procedures shall include:

   (1) Instructions for responding to equipment failure and the names of the individuals responsible for implementing corrective actions;

   (2) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

   (3) The names and telephone numbers of the authorized user (AU), the authorized medical physicist (AMP), and the RSO to be contacted if the unit or the console operates abnormally.

2. A copy of the procedures required by subdivision 1 d of this subsection shall be physically located at the unit console.

3. Licensees shall post instructions at the unit console to inform the operator of:

a. The location of the procedures required by subdivision 1 d of this subsection; and

b. The names and telephone numbers of the AU, the AMP, and the RSO to be contacted if the unit or console operates abnormally.

4. Licensees shall provide instruction and document initially and at least annually to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:

a. The procedures identified in subdivision 1 d of this subsection; and

b. The operating procedures for the unit.

5. Licensees shall ensure that operators, authorized users, and authorized medical physicists participate in drills of the emergency procedures initially and at least annually and document the exercise.

B. Safety procedures for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

1. Licensees shall control access to the treatment room by a door at each entrance.

2. Licensees shall equip each entrance to the treatment room with an electrical interlock system that will:

a. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

b. Cause the source to be shielded when an entrance door is opened; and

c. Prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off console is reset at the console.

3. Licensees shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

4. Except for low-dose remote afterloader units, licensees shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

5. For licensed activities where sources are placed within the patient's or human research subject's body, licensees shall only conduct treatments that allow for expeditious removal of a decoupled or jammed source.

6. In addition to the requirements specified in subdivisions 1 through 5 of this subsection, licensees shall:

a. For medium dose-rate and pulsed dose-rate remote afterloader units, require:

(1) An AMP and either an AU or an physician under the supervision of an AU who has been trained to the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the units; and

(2) An AMP and either an AU or an individual under the supervision of an AU who has been trained to remove the source applicators in the event of an emergency involving the unit to be immediately available during the continuation of all patient treatments involving the unit.

b. For high dose-rate remote afterloader units, require:

(1) An AU and an AMP to be physically present during the initiation of all patient treatments involving the unit; and

(2) An AMP and either an AU or a physician under the supervision of an AU who has been trained in the operation and emergency response for the unit to be physically present during continuation of all patient treatments involving the unit.

c. For gamma stereotactic radiosurgery units, require an AU and an AMP to be physically present throughout all patient treatments involving the unit.

d. Notify the RSO, or his designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

7. Licensees shall have applicable emergency response equipment available near each treatment room to respond to a source that:

a. Remains in the unshielded position; or

b. Lodges within the patient following completion of the treatment.

12VAC5-481-2044. Dosimetry Equipment.

A. Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, licensees shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met.

1. The system shall have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration shall have been performed within the previous two years and after any servicing that may have affected system calibration; or

2. The system shall have been calibrated within the previous four years. 18 to 30 months after that calibration, the system shall have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison shall indicate that the calibration factor of the licensee's system had not changed by more than 2.0%. The licensee

may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

B. Licensees shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with subsection A of this section. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in subsection A of this section.

12VAC5-481-2045. Full Calibration Measurements.

A. Teletherapy units.

1. Licensees authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

a. Before the first medical use of the unit;

b. Before medical use under the following conditions:

(1) Whenever spot-check measurements indicate that the output differs by more than 5.0% from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(2) Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and

(3) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

c. At intervals not exceeding one year.

2. To satisfy the requirement of subdivision 1 of this subsection, full calibration measurements shall include determination of:

a. The output within plus or minus 3.0% for the range of field sizes and for the distance or range of distances used for medical use;

b. The coincidence of the radiation field and the field indicated by the light beam localizing device;

c. The uniformity of the radiation field and its dependence on the orientation of the useful beam;

d. Timer accuracy and linearity over the range of use;

e. On-off error; and

f. The accuracy of all distance measuring and localization devices in medical use.

3. Licensees shall use the dosimetry system described in 12VAC5-481-2044 to measure the output for one set of exposure conditions. The remaining radiation measurements required in subdivision 2 a of this subsection may be made using a dosimetry system that indicates relative dose rates.

4. Licensees shall make full calibration measurements required by subdivision 1 of this subsection in accordance with published protocols accepted by nationally recognized bodies.

5. Licensees shall mathematically correct the outputs determined in subdivision 2 a of this subsection for physical decay for intervals not exceeding one month for cobalt-60, six months for cesium-137, or at intervals consistent with 1.0% decay for all other nuclides.

6. Full calibration measurements required by subdivision 1 of this subsection and physical decay corrections required by subdivision 5 of this subsection shall be performed by the authorized medical physicist (AMP).

B. Remote afterloader units.

1. Licensees authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

a. Before the first medical use of the unit;

b. Before medical use under the following conditions:

(1) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(2) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly;

c. At intervals not exceeding one quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

d. At intervals not exceeding one year for low dose-rate remote afterloader units.

2. To satisfy the requirement of subdivision 1 of this subsection, full calibration measurements shall include, as applicable, determination of:

a. The output within plus or minus 5.0%;

b. Source positioning accuracy to within plus or minus 1 millimeter;

c. Source retraction with backup battery upon power failure;

d. Length of the source transfer tubes;

e. Timer accuracy and linearity over the typical range of use;

f. Length of the applicators; and

g. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

3. Licensees shall use the dosimetry system described in 12VAC5-481-2044 to measure the output.

4. Licensees shall make full calibration measurements required by subdivision 1 of this subsection in accordance with published protocols accepted by nationally recognized bodies.

5. In addition to the requirements for full calibrations for low dose-rate remote afterloader units in subdivision 2 of this subsection, licensees shall perform an autoradiograph of the sources to verify inventory and source arrangement at intervals not exceeding one calendar quarter.

6. For low dose-rate remote afterloader units, licensees may use measurements provided by the source manufacturer that are made in accordance with subdivisions 1 through 5 of this subsection.

7. Licensees shall mathematically correct the outputs determined in subdivision 2 a of this subsection for physical decay at intervals consistent with 1.0% physical decay.

8. Full calibration measurements required by subdivision 1 of this subsection and physical decay corrections required by subdivision 7 of this subsection shall be performed by the AMP.

C. Gamma stereotactic radiosurgery units.

1. Licensees authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

a. Before the first medical use of the unit;

b. Before medical use under the following conditions:

(1) Whenever spot-check measurements indicate that the output differs by more than 5.0% from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(2) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(3) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

c. At intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

2. To satisfy the requirement of subdivision 1 of this subsection, full calibration measurements shall include determination of:

a. The output within plus or minus 3.0%;

b. Relative helmet factors;

c. Isocenter coincidence;

d. Timer accuracy and linearity over the range of use;

e. On-off error;

f. Trunnion centricity;

g. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

h. Helmet microswitches;

i. Emergency timing circuits; and

j. Stereotactic frames and localizing devices (trunnions).

3. Licensees shall use the dosimetry system described in 12VAC5-481-2044 to measure the output for one set of exposure conditions. The remaining radiation measurements required in subdivision 2 a of this subsection may be made using a dosimetry system that indicates relative dose rates.

4. Licensees shall make full calibration measurements required by subdivision 1 of this subsection in accordance with published protocols accepted by nationally recognized bodies.

5. Licensees shall mathematically correct the outputs determined in subdivision 2 a of this subsection at intervals not exceeding one month for cobalt-60 and at intervals consistent with 1.0% physical decay for all other radionuclides.

6. Full calibration measurements required by subdivision 1 of this subsection and physical decay corrections required by subdivision 5 of this subsection shall be performed by the AMP.

12VAC5-481-2046. Periodic Spot-Checks.

A. Periodic spot-checks for teletherapy units.

1. Licensees authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

a. Timer accuracy and timer linearity over the range of use;

b. On-off error;

c. The coincidence of the radiation field and the field indicated by the light beam localizing device;

d. The accuracy of all distance measuring and localization devices used for medical use;

e. The output for one typical set of operating conditions measured with the dosimetry system described in 12VAC5-481-2044; and

f. The difference between the measurement made in subdivision 1 e of this subsection and the anticipated output, expressed as a percentage of the anticipated output (i.e. the value obtained at last full calibration corrected mathematically for physical decay).

2. Licensees shall perform measurements required by subdivision 1 of this subsection in accordance with written procedures established by the authorized medical physicist (AMP). That individual need not actually perform the spot-check measurements.

3. Licensees shall have the AMP review the results of each spot-check within 15 days. The shall notify the licensee as soon as possible in writing of the results of each spot-check.

4. Licensees authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

a. Electrical interlocks at each teletherapy room entrance;

b. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam on-off mechanism);

c. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

d. Viewing and intercom systems;

e. Treatment room doors from inside and outside the treatment room; and

f. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

5. If the results of the checks required in subdivision 4 of this subsection indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

B. Periodic spot-checks for remote afterloader units.

1. Licensees authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit:

a. Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

b. Before each patient treatment with a low dose-rate remote afterloader unit; and

c. After each source installation.

2. Licensees shall perform the measurements required by subdivision 1 of this subsection in accordance with written procedures established by the AMP. That individual need not actually perform the spot-check measurements.

3. Licensees shall have the authorized medical physicist review the results of each spot-check within 15 days. The AMP shall notify the licensee as soon as possible in writing of the results of each spot-check.

4. To satisfy the requirements of subdivision 1 of this subsection, spot-checks shall, at a minimum, assure proper operation of:

a. Electrical interlocks at each remote afterloader unit room entrance;

b. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

c. Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

d. Emergency response equipment;

e. Radiation monitors used to indicate the source position;

f. Timer accuracy;

g. Clock (date and time) in the unit's computer; and

h. Decayed sources activity in the unit's computer.

5. If the results of the checks required in subdivision 4 of this subsection indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

C. Periodic spot-checks for gamma stereotactic radiosurgery units.

1. Licensees authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

a. Monthly;

b. Before the first use of the unit on a given day; and

c. After each source installation.

2. Licensees shall:

a. Perform the measurements required by subdivision 1 of this subsection in accordance with written procedures established by the AMP. That individual need not actually perform the spot-check measurements.

b. Have the AMP review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

3. To satisfy the requirements of subdivision 1 a of this subsection, spot-checks shall, at a minimum:

a. Assure proper operation of:

(1) Treatment table retraction mechanisms, using backup battery power or hydraulic backups with the unit off;

(2) Helmet microswitches;

(3) Emergency timing circuits; and

(4) Stereotactic frames and localizing devices (trunnions).

b. Determine the following:

(1) The output for one typical set of operating conditions measured with the dosimetry system described in 12VAC5-481-2044 ;

(2) The difference between the measurement made in subdivision 3 b (1) of this subsection and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(3) Source output against computer calculation;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error; and

(6) Trunnion centricity.

4. To satisfy the requirements of subdivisions 1 b and 1 c of this subsection, spot-checks shall assure proper operation of:

a. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

b. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

c. Viewing and intercom systems;

d. Timer termination;

e. Radiation monitors used to indicate room exposures; and

f. Emergency off buttons.

5. A licensee shall arrange for the repair of any system identified in subdivision 3 of this subsection that is not operating properly as soon as possible.

6. If the results of the checks required in subdivision 4 of this subsection indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

12VAC5-481-2047. Additional Technical Requirements for Mobile Remote Afterloader Units.

A. Licensees providing mobile remote afterloader service shall:

1. Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

2. Account for all sources before departure from a client's address of use.

B. In addition to the periodic spot-checks required by 12VAC5-481-2046 , licensees authorized to use a mobile remote afterloader for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks shall be made to verify the operation of:

1. Electrical interlocks on treatment area access points;

2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

3. Viewing and intercom systems;

4. Applicators, source transfer tubes, and transfer tube-applicator interfaces;

5. Radiation monitors used to indicate room exposures;

6. Source positioning (accuracy); and

7. Radiation monitors used to indicate whether the source has returned to a safe shielded position.

C. In addition to the requirements for checks in subsection B of this section, licensees shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

D. If the results of the checks required in subsection B of this section indicate the malfunction of any system, licensees shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

12VAC5-481-2048. Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

A. Licensees shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

B. This inspection and servicing may only be performed by person specifically licensed to do so by the agency, the NRC, or another agreement state.

12VAC5-481-2049. Therapy-Related Computer Systems.

Licensees shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of:

1. The source-specific input parameters required by the dose calculation algorithm;

2. The accuracy of dose, dwell time, and treatment time calculations at representative points;

3. The accuracy of isodose plots and graphic displays;

4. The accuracy of the software used to determine sealed source positions from radiographic images; and

5. The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

12VAC5-481-2050. (Repealed.)

Article 10. Training and Experience Requirements

12VAC5-481-2060. Other Medical Uses of Radioactive Material or Radiation from Radioactive Materials.

Article 11. Other Medical Uses of Byproduct Material or Radiation from Byproduct Material

Licensees may use radioactive material or a radiation source approved for medical use that is not specifically addressed in Articles 3 (12VAC5-481-1700 et seq.) through 9 (12VAC5-481-2040 et seq.) of this part if:

1. The applicant or licensee has submitted the information required by 12VAC5-481-1680; and

2. The applicant or licensee has received written approval from the agency in a license or license amendment and uses the material in accordance with this chapter and specific conditions the agency considers necessary for the medical use of the material.

12VAC5-481-2070. Records.

Article 12. Records

A. Records of authority and responsibilities for radiation protection programs.

1. Licensees shall retain a record of actions taken by the licensee's management in accordance with 12VAC5-481-1700 for five years. The record shall include a summary of

the actions taken and a signature of licensee management.

2. Licensees shall retain a copy of both authority, duties, and responsibilities of the RSO as required by 12VAC5-481-1700 and a signed copy of each RSO's agreement to be responsible for implementing the radiation safety program, as required by 12VAC5-481-1700 , for the duration of the license. The records shall include the signature of the RSO and licensee management.

B. Records of radiation protection program changes. Licensees shall retain a record of each radiation protection program change made in accordance with 12VAC5-481-1700 F for five years. The record shall include a copy of the old and new procedures, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

C. Records of written directives. Licensees shall retain a copy of each written directive as required by 12VAC5-481-1720 for three years.

D. Records for procedures for administrations requiring written directive. Licensees shall retain a copy of the procedures required by 12VAC5-481-1730 for the duration of the license.

E. Records of dosages of unsealed radioactive material for medical use. Licensees shall maintain a record of dosage determinations required by 12VAC5-481-1820 for three years. The record shall contain the radiopharmaceutical; the patient's or human research subject's name or identification number if one has been assigned; the prescribed dosage, the determined dosage, or a notation that the total activity is less than 30 µCi (1.1 MBq); the date and time of dosage determination; and the name of the individual who determined the dosage.

F. Records of leak tests and inventory of sealed sources and brachytherapy sources.

1. Licensees shall retain records of leak tests required by 12VAC5-481-1840 for three years. The records shall include the model number, and the serial number, if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

2. Licensees shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by 12VAC5-481-1840 for three years. The inventory records shall contain the model number of each source, and serial number of each source if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

G. Records of surveys for ambient radiation exposure rate. Licensees shall retain a record of each survey required by 12VAC5-481-1860 for three years. The record shall include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

H. Records of the release of individuals containing unsealed radioactive material or implants containing radioactive material.

1. Licensees shall retain a record signed by the authorized user of the basis for authorizing the release of an individual in accordance with 12VAC5-481-1870 for three years after the date of release if the total effective dose equivalent is calculated by:

a. Using the retained activity rather than the activity administered;

b. Using an occupancy factor less than 0.25 at 1 meter;

c. Using the biological or effective half-life; or

d. Considering the shielding by tissue.

2. Licensees shall retain a record for three years after the date of release of the instruction required by 12VAC5-481-1870 that were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 500 mrem (5 mSv).

I. Records of mobile medical services.

1. Licensees shall retain a copy of each letter that permits the use of radioactive material at the client's address, as required by 12VAC5-481-1880 . Each letter shall clearly delineate the authority and responsibility of the licensee and the client and shall be retained for three years after the last provision of service.

2. Licensees shall retain the record of each survey required by 12VAC5-481-1880 for three years. The record shall include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

J. Records of decay-in-storage. Licensees shall maintain records of the disposal of licensed materials, as required by 12VAC5-481-1890 for three years. The record shall include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

K. Records of molybdenum-99, strontium-82 and strontium-85 concentrations. Licensee shall maintain a record of molybdenum-99 concentration or strontium-82 and stontrium-85 concentration tests required by 12VAC5-481-1930 for three years. The record shall include:

1. For each measured elution of technetium-99m, the ratio of measures expressed as microcuries of molybdenum-99 per millicurie of technetium-99m or kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m, the time and date of the measurement, and the name of the individual who made the measurement; or

2. For each measured elution of rubidium-82, the ratio of the measures expressed as microcurie of strontium-82 per millicurie of rubidium-82 or kilobecquerel of strontium-82 per megabecquerel of rubidium-82, microcurie of strontium-85 per millicurie of rubidium-82 or kilobecquerel of strontium-85 per megabecquerel of rubidium-82, the time and date of the measurement, and the name of the individual who made the measurement.

L. Records of safety instruction. Licensees shall maintain a record of safety instructions and training required by 12VAC5-481-1960 and 12VAC5-481-1970 for three years. Each record shall include a list of topics covered, the date of the instruction or training, the names of the attendees, and the names of the individuals who provided the instruction.

M. Records of surveys after source implant and removal. Licensees shall maintain a record of the surveys required by 12VAC5-481-2011 and 12VAC5-481-2041 for three years. Each record shall include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

N. Records of brachytherapy source accountability.

1. Licensee shall maintain a record of brachytherapy source accountability required by 12VAC5-481-2012 for three years.

2. For temporary implants, the record shall include the number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use and the number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

3. For permanent implants, the record shall include the number and activity of sources removed from storage, the date they were removed from storage, the name of the individual who removed them from storage, the number and activity of sources not implanted, the date they were returned to storage, the name of the individual who returned them to storage, and the number and activity of sources permanently implanted in the patient or human research subject.

O. Records of calibration measurements of brachytherapy sources. Licensees shall maintain a record of the calibrations of brachytherapy sources required by 12VAC5-481-2015 for three years after the last use of the source. The record shall include the date of the calibration; the manufacturer's name, model number and serial number for the source and the instruments used to calibrate the source; the source output or activity; the source positioning accuracy within the applicators; and the name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

P. Records of decay of strontrium-90 sources for ophthalmic treatments. Licensees shall maintain a record of the activity of a strontium-90 source required by 12VAC5-481-2016 for the life of the source. The record shall include the date and initial activity of the source as determined under 12VAC5-481-2016 , and for each decay calculation, the date and the source activity as determined under 12VAC5-481-2016 and the signature of the authorized medical physicist.

Q. Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. Licensees shall retain a record of the installation, adjustment, maintenance, and repair of remote afterloaders units, teletherapy units, and gamma stereotactic radiosurgery units as required by 12VAC5-481-2042 for three years. For each installation, adjustment, maintenance, and repair, the record

shall include the date, description of the service, and names of the individuals who performed the work.

R. Records of safety procedures. Licensees shall retain a copy of the procedures required by 12VAC5-481-2043 until the licensee no longer possesses the remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

S. Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. Licensees shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with 12VAC5-481-2044 for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date; the manufacturer's name, model numbers, and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 12VAC5-481-2044; the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and the names of the individuals who performed the calibration, intercomparison, or comparison.

T. Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations. Licensees shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by 12VAC5-481-2045 for three years. The record shall include the date of calibration; the manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit, the source, and the instruments used to calibrate the unit; the results and an assessment of the full calibrations; the results of the autoradiograph required for low dose-rate remote afterloader units; and the signature of the authorized medical physicist who performed the full calibration.

U. Records of periodic spot-checks for teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units.

1. Licensees shall retain a record of each periodic spot-check for teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units required by 12VAC5-481-2046 for three years. The record shall include:

a. For each teletherapy unit; the date of the spot-check, the manufacturer's name, model number, and serial number, source, and instrument used to measure the output of the teletherapy unit; an assessment of timer linearity and constancy; the calculated on-off error; a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; the determined accuracy of each distance measuring and localization device; the difference between the anticipated output and the measured output; notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; the name of the individual who performed the periodic spot-check; and the signature of the authorized medical physicist who reviewed the record of the spot-check.

b. For each remote afterloader unit: the date of the spot-check, the manufacturer's

name, model and serial number for the remote afterloader unit and source; an assessment of timer accuracy; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; the name of the individual who performed the periodic spot-check; and the signature of the authorized medical physicist who reviewed the record of the spot-check.

c. For each gamma stereotactic radiosurgery unit: the date of the spot-check, the manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit; an assessment of timer linearity and accuracy; the calculated on-off error; a determination of trunnion centricity; the difference between the anticipated output and the measured output; an assessment of source output against computer calculations; notations indicating the operability of radiation monitors; helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems; timer termination, treatment table retraction mechanism, and stereotactic frames and localizing device (trunnions); the name of the individual who performed the periodic spot-check; and the signature of the authorized medical physicist who reviewed the record of the spot-check.

2. Licensees shall retain a copy of the procedures required by 12VAC5-481-2046 A 2, 12VAC5-481-2046 B, and 12VAC5-481-2046 C 2 until the licensee no longer possesses the teletherapy unit, remote afterloader unit, or gamma stereotactic radiosurgery unit.

V. Records of additional technical requirements for mobile remote afterloader units. Licensees shall retain a record of each check for mobile remote afterloader units required by 12VAC5-481-2047 for three years. The record shall include the date of the check, the manufacturer's name, model number, and serial number of the remote afterloader unit; notations accounting for all sources before the licensee departs from a facility; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces; source positioning accuracy; and the signature of the individual who performed the check.

W. Records of surveys of therapeutic treatment units. Licensees shall maintain a record of radiation surveys of treatment units made in accordance with 12VAC5-481-2041 for the duration of use of the unit. The record shall include the date of the measurements, the manufacturer's name, model number, and serial number of the treatment unit; source and instrument used to measure radiation levels; each dose rate measured around the source while the unit is in the off position and the average of all measurements; and the signature of the individual who performed the test.

X. Records of five-year inspection for teletherapy and gamma stereotactic radiosurgery units. Licensees shall maintain a record of the five-year inspections for teletherapy and gamma stereotactic radiosurgery required by 12VAC5-481-2048 for the duration of use of the unit. The record shall include the inspector's radioactive materials license number, the date of inspection, the manufacturer's name, model number, and serial number of both the

treatment unit and source, a list of components inspected and serviced, the type of service, and the signature of the inspector.

12VAC5-481-2080. Reports.

Article 13. Reports

A. Report and notification of a medical event.

1. Licensees shall report any event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material results in:

a. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin; and

(1) The total dose delivered differs from the prescribed dose by 20% or more;

(2) The total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range; or

(3) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more.

b. A dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the following:

(1) An administration of a wrong radioactive drug containing radioactive material;

(2) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

(3) An administration of a dose or dosage to the wrong individual or human research subject;

(4) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(5) A leaking sealed source.

c. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) to an organ or tissue and 50% or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

2. Licensees shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

3. Licensees shall notify the agency by telephone no later than the next calendar day after

discovery of the medical event.

4. By an appropriate method listed in 12VAC5-481-150 , licensees shall submit a written report to the agency within 15 days after discovery of the medical event.

a. The written report shall include:

(1) The licensee's name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

(4) Why the event occurred;

(5) The effect, if any, on the individuals who received the administration;

(6) What actions, if any, have been taken or are planned to prevent recurrence; and

(7) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

b. The report may not contain the individual's name or any other information that could lead to identification of the individual.

5. Licensees shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. Licensees are not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, licensees shall notify the individual as soon as possible thereafter. Licensees may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this subdivision, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, licensees shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. Licensees shall provide such a written description if requested.

6. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

7. Licensees shall:

a. Annotate a copy of the report provided to the agency with the:

(1) Name of the individual who is the subject of the event; and

(2) Social security number or other identification number, if one has been assigned, of

the individual who is the subject of the event; and

b. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

B. Report and notification of a dose to an embryo/fetus or a nursing child.

1. Licensees shall report any dose to an embryo/fetus that is greater than 500 mrem (5 mSv) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

2. Licensees shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:

a. Is greater than 5 mSv (500 rem) total effective dose equivalent; or

b. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

3. Licensees shall notify the agency by telephone no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in accordance with subdivision 1 or 2 in this subsection.

4. By an appropriate method listed in 12VAC5-481-150 , licensees shall submit a written report to the agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in subdivision 1 or 2 of this subsection.

a. The written report shall include

(1) The licensee's name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

(4) Why the event occurred;

(5) The effect, if any, on the embryo/fetus or the nursing child;

(6) What actions, if any, have been taken or are planned to prevent recurrence; and

(7) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

b. The report shall not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

5. Licensees shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as "mother," no later than 24 hours after discovery of an event that would require reporting under subdivisions 1 or 2 of this subsection, unless the referring physician personally informs the licensee either that the mother will be informed or that, based on medical judgment, telling the mother

would be harmful. Licensees are not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, licensees shall make the appropriate notifications as soon as possible thereafter. Licensees may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this subdivision, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, licensees shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. Licensees shall provide such a written description if requested.

6. Licensees shall:

a. Annotate a copy of the report provided to the agency with the:

(1) Name of the pregnant individual or the nursing child who is the subject of the event; and

(2) Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

b. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

C. Report of a leaking source.

1. Licensees shall file a report within five days if a leak test required by 12VAC5-481-1840 reveals the presence of 0.005 µCi (185 Bq) or more of removable contamination.

2. The report shall be filed with the agency by an appropriate method listed in 12VAC5-481-150 . The written report shall include:

a. The model number and serial number, if assigned, of the leaking source;

b. The radionuclide and its estimated activity;

c. The results of the test;

d. The date of the test; and

e. The action taken.

12VAC5-481-2090. Purpose and Scope.

Part VIII. Radiation Safety Requirements For Analytical X-Ray Equipment

This part provides special requirements for analytical X-ray equipment. The requirements of this part are in addition to, and not in substitution for, applicable requirements in other parts of these regulations.

12VAC5-481-2100. Equipment Requirements.

A. Safety device. A device that prevents the entry of any portion of an individual's body into the primary X-ray beam path or that causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant may apply to the agency for an exemption from the requirement of a safety device. Such application shall include:

1. A description of the various safety devices that have been evaluated;

2. The reason each of these devices cannot be used; and

3. A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

B. Warning devices.

1. Open-beam configurations shall be provided with a readily discernible indication of:

a. X-ray tube "on-off" status located near the radiation source housing, if the primary beam is controlled in this manner; and/or

b. Shutter "open-closed" status located near each port on the radiation source housing, if the primary beam is controlled in this manner.

2. An easily visible warning light labeled with the words "X-RAY ON,"or words having a similar intent, shall be located:

a. Near any switch that energizes an X-ray tube and shall be illuminated only when the tube is energized; or

b. In the case of a radioactive source, near any switch that opens a housing shutter and shall be illuminated only when the shutter is open.

3. Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after September 20, 2006, warning devices shall have fail-safe characteristics.

C. Ports. Unused ports on radiation source housings shall be secured in the closed position in a manner that will prevent casual opening.

D. Labeling. All analytical X-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

1. "CAUTION—HIGH INTENSITY X-RAY BEAM," or words having a similar intent, on the X-ray source housing; and

2. "CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an X-ray tube if the radiation source is an X-ray tube; or

3. "CAUTION—RADIOACTIVE MATERIAL", or words having a similar intent, on the source housing in accordance with 12VAC5-481-660 if the radiation source is a radionuclide.

E. Shutters. On open-beam configurations installed after September 20, 2006, each port on

the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

F. Radiation source housing. Each radiation source housing shall be subject to the following requirements:

1. Each X-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.

2. Each radioactive source housing or port cover or each X-ray tube housing shall be so constructed that, with all shutters closed, the radiation measured at a distance of five centimeters from its surface is not capable of producing a dose in excess of 2.5 millirems (0.025 mSv) in one hour. For systems utilizing X-ray tubes, this limit shall be met at any specified tube rating.

G. Generator cabinet. Each X-ray generator shall be supplied with a protective cabinet that limits leakage radiation measured at a distance of five centimeters from its surface such that it is not capable of producing a dose in excess of 0.25 millirem (2.5 μSv) in one hour.

12VAC5-481-2110. Area Requirements.

A. Radiation Levels. The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group that could result in a dose to an individual present therein in excess of the dose limits given in 12VAC5-481-640 . For systems utilizing x-ray tubes, these levels shall be met at any specified tube rating.

B. Surveys.

1. Radiation surveys, as required by 12VAC5-481-750 , of all analytical x-ray systems sufficient to show compliance with 12VAC5-481-2440 A shall be performed:

a. Upon installation of the equipment, and at least once every five years thereafter by or under the supervision of a private or state inspector who is physically present at the facility during the inspection in order to assure compliance with this chapter;

b. Following any change in the initial arrangement, number, or type of local components in the system;

c. Following any maintenance requiring the disassembly or removal of a local component in the system;

d. During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed;

e. Any time a visual inspection of the local components in the system reveals an abnormal condition; and

f. Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 12VAC5-481-

630 .

2. Radiation survey measurements shall not be required if a registrant (or licensee) can demonstrate compliance with subsection A of this section to the satisfaction of the agency.

C. Posting. Each area or room containing analytical x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION—X-RAY EQUIPMENT" or words having a similar intent in accordance with 12VAC5-481-660 .

12VAC5-481-2120. Operating Requirements.

A. Procedures. Normal operating procedures shall be written and available to all analytical X-ray equipment workers. No individual shall be permitted to operate analytical X-ray equipment in any manner other than that specified in the procedures unless such individual has obtained written approval of the radiation safety officer.

B. Bypassing. No individual shall bypass a safety device or interlock unless such individual has obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device or interlock has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING", or words having a similar intent, shall be placed on the radiation source housing.

C. Repair or modification of X-ray tube systems. Except as specified in 12VAC5-481-2450 B, no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

D. Radioactive source replacement, testing, or repair. Radioactive source housings shall be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the Nuclear Regulatory Commission, an agreement state, or a licensing state.

12VAC5-481-2130. Personnel Requirements.

A. Instruction. No individual shall be permitted to operate or maintain analytical X-ray equipment unless such individual has received instruction in and demonstrated competence as to:

1. Identification of radiation hazards associated with the use of the equipment;

2. Significance of the various radiation warning, safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

3. Proper operating procedures for the equipment;

4. Recognition of symptoms of an acute localized exposure; and

5. Proper procedures for reporting an actual or suspected exposure.

B. Personnel monitoring.

1. Finger or wrist dosimetric devices shall be provided to and shall be used by:

a. Analytical X-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and

b. Personnel maintaining analytical X-ray equipment if the maintenance procedures require the presence of a primary X-ray beam when any local component in the analytical X-ray system is disassembled or removed.

2. Reported dose values shall not be used for the purpose of determining compliance with 12VAC5-481-630 of these regulations unless evaluated by a private inspector.

12VAC5-481-2140. Purpose and Scope.

Part IX. Radiation Safety Requirements For Particle Accelerators

Article 1. Purpose and Scope

A. This part establishes procedures for the registration and the use of particle accelerators.

B. In addition to the requirements of this part, all registrants are subject to the requirements of Parts I (12VAC5-481-10 et seq.), II (12VAC5-481-260 et seq.), III (12VAC5-481-380 et seq.), IV (12VAC5-481-600 et seq.), and X (12VAC5-481-2250 et seq.) of this chapter. Registrants engaged in industrial radiographic operations are subject to the requirements of Part V (12VAC5-481-1170 et seq.) of this chapter, and registrants engaged in the healing arts are subject to the requirements of Parts VI (12VAC5-481-1580 et seq.) and VII (12VAC5-481-1660 et seq.) of this chapter. Registrants whose operations result in the production of radioactive material are subject to the requirements of Part III (12VAC5-481-380 et seq.) of this chapter.

12VAC5-481-2150. Registration Requirements.

Article 2. Registration Procedures

No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration issued pursuant to Part II (12VAC5-481-260 et seq.) or III (12VAC5-481-380 et seq.) of this chapter.

12VAC5-481-2160. General Requirements for the Issuance of a Registration for Particle Accelerators.

In addition to the requirements of Part II (12VAC5-481-260 et seq.) or III (12VAC5-481-380 et seq.) of this chapter, a registration application for use of a particle accelerator will be approved only if the agency determines that:

1. The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this part and Parts IV (12VAC5-481-600 et seq.) and X (12VAC5-481-2250 et seq.) of this chapter in such a manner as to

minimize danger to public health and safety or property;

2. The applicant's proposed or existing equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;

3. The issuance of the registration will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in 12VAC5-481-2170;

4. The applicant has appointed a radiation safety officer;

5. The applicant and the applicant's staff have substantial experience in the use of particle accelerators and training sufficient for application to its intended uses;

6. The applicant has established a radiation safety committee to approve, in advance, proposals for uses of particle accelerators, whenever deemed necessary by the agency; and

7. The applicant has an adequate training program for operators of particle accelerators.

12VAC5-481-2170. Human Use of Particle Accelerators.

In addition to the requirements of Part II (12VAC5-481-260 et seq.) of this chapter, a registration for use of a particle accelerator in the healing arts will be issued only if:

1. The applicant has appointed a medical committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of a particle accelerator whenever deemed necessary by the agency. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in depth dose calculations and protection against radiation;

2. The individuals designated on the application as the users have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans; and

3. The individual designated on the application as the user is a physician.

12VAC5-481-2180. Limitations.

Article 3. Radiation Safety Requirements for Use of Particle Accelerators

A. No registrant shall permit any individual to act as an operator of a particle accelerator until such individual:

1. Has been instructed in radiation safety and shall have demonstrated an understanding thereof;

2. Has received copies of and instruction in this part and the applicable requirements of Parts IV (12VAC5-481-600 et seq.) and X (12VAC5-481-2250 et seq.) of this chapter, pertinent registration conditions and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

3. Has demonstrated competence to use the particle accelerator, related equipment, and

survey instruments that will be employed.

B. The radiation safety committee or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to minimize danger to public health and safety or property.

12VAC5-481-2190. Shielding and Safety Design Requirements.

A. A private inspector, acceptable to the agency, shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.

B. Each particle accelerator installation shall be provided with such primary and secondary barriers as are necessary to assure compliance with 12VAC5-481-630 .

12VAC5-481-2200. Particle Accelerator Controls and Interlock Systems.

A. Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified and easily discernible.

B. Each entrance into a target room or other high radiation area shall be provided with a safety interlock that shuts down the machine under conditions of barrier penetration.

C. Each safety interlock shall be on a circuit that shall allow it to operate independently of all other safety interlocks.

D. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.

E. When a safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the safety interlock has been tripped and, lastly, at the main control console.

F. A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

12VAC5-481-2210. Warning Devices.

A. Each location designated as a high radiation area, and each entrance to such location, shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

B. Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of such high radiation area. Such warning device shall be clearly discernible in all high radiation areas.

C. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be

posted in accordance with 12VAC5-481-660 .

12VAC5-481-2220. Operating Procedures.

A. Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

B. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

C. All safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed three months. Results of such tests shall be maintained at the accelerator facility for inspection by the agency.

D. Electrical circuit diagrams of the accelerator and the associated safety interlock systems shall be kept current and maintained for inspection by the agency and shall be available to the operator at each accelerator facility.

E. If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

1. Authorized by the radiation safety committee or radiation safety officer;

2. Recorded in a permanent log and a notice posted at the accelerator control console; and

3. Terminated as soon as possible.

F. A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel.

12VAC5-481-2230. Radiation Monitoring Requirements.

A. There shall be available at each particle accelerator facility appropriate portable monitoring equipment that is operable and has been appropriately calibrated for the radiations being produced at the facility. Such equipment shall be tested for proper operation daily and calibrated at intervals not to exceed one year and after each servicing and repair.

B. A radiation survey shall be performed and documented by a private inspector, acceptable to the agency, when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

C. Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

D. All area monitors shall be calibrated at intervals not to exceed one year and after each servicing and repair.

E. Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present.

F. Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination.

G. All surveys shall be made in accordance with the written procedures established by a private inspector, acceptable to the agency, or the radiation safety officer.

H. Records of all radiation protection surveys, calibrations, and instrumentation tests shall be maintained at the accelerator facility.

12VAC5-481-2240. Ventilation Systems.

A. Ventilation systems shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in Appendix B to 10 CFR Part 20.

B. A registrant, as required in Appendix B to 10 CFR Part 20 shall not vent, release, or otherwise discharge airborne radioactive material to an unrestricted area which exceeds the limits specified in Appendix B to 10 CFR Part 20, except as authorized pursuant to 12VAC5-481-730 . For purposes of this subsection concentrations may be averaged over a period not greater than one year. Every effort should be made to maintain releases of radioactive material to unrestricted areas as far below these limits as is reasonably achievable.

12VAC5-481-2250. Purpose and Scope.

Part X. Notices, Instructions, and Reports to Workers; Inspections

This part establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in activities under a license or registration and options available to such individuals in connection with agency inspections of licensees or registrants to ascertain compliance with the provisions of the Act and regulations, orders, and licenses issued thereunder regarding radiological working conditions. The regulations in this part apply to all persons who receive, possess, use, own, or transfer sources of radiation registered with or licensed by the agency pursuant to Parts II (12VAC5-481-260 et seq.) and III (12VAC5-481-380 et seq.) of this chapter.

12VAC5-481-2260. Posting of Notices to Workers.

A. Each licensee or registrant shall post current copies of the following documents:

1. The regulations in this part and in Part IV (12VAC5-481-600 et seq.) of this chapter;

2. The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;

3. The operating procedures applicable to activities under the license or registration;

4. Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to Part I (12VAC5-481-10 et seq.) of this chapter, and any response from the licensee or registrant; and

5. Agency form "Notice to Employees" as required by these regulations.

B. If posting of a document specified in subdivisions A 1 through 3 of this section is not

practicable, the licensee or registrant may post a notice that describes the document and states where it may be examined.

C. Agency documents posted pursuant to subdivision A 4 of this section shall be posted within two working days after receipt of the documents from the agency; the licensee's or registrant's response, if any, shall be posted within five working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

D. Documents, notices, or forms posted pursuant to this section shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

12VAC5-481-2270. Instructions to Workers.

A. All individuals likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem):

1. Shall be kept informed of the storage, transfer, or use of sources of radiation in the licensee's or registrant's workplace;

2. Shall be instructed in the health protection problems associated with exposure to radiation or radioactive material to the individual and potential offspring, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

3. Shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of these regulations and licenses for the protection of personnel from exposures to radiation or radioactive material;

4. Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition that may constitute, lead to, or cause a violation of the Act, these regulations, or license condition, or any unnecessary exposure to radiation or radioactive material;

5. Shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

6. Shall be advised as to the radiation exposure reports that workers shall be furnished pursuant to 12VAC5-481-2280 .

B. The extent of these instructions shall be commensurate with potential radiological health protection problems present in the workplace.

C. The instructions listed in subsection A of this section shall be given at least annually to said individuals.

12VAC5-481-2280. Notifications and Reports to Individuals.

A. Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this section. The information reported shall include data and results obtained pursuant to these regulations, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to 12VAC5-481-1040 . Each notification and report shall:

1. Be in writing;

2. Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number;

3. Include the individual's exposure information; and

4. Contain the following statement:

"This report is furnished to you under the provisions of Part X (12VAC5-481-2250 et seq.) of 12VAC5-481 , Virginia Radiation Protection Regulations. You should preserve this report for further reference."

B. Each licensee shall make dose information available to workers as shown in records maintained by the licensee under the provisions of 12VAC5-481-1040 . The licensee shall provide an annual report to each individual monitored under 12VAC5-481-760 of the dose received in that monitoring year if:

1. The individual's occupational dose exceeds 100 mrem (1 mSv) TEDE or 100 mrem (1 mSv) to any individual organ or tissue; or

2. The individual requests his annual dose report.

C. Each licensee or registrant shall furnish a written report of the worker's exposure to sources of radiation at the request of a worker formerly engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to 12VAC5-481-760 . Such report shall be furnished within 30 days from the date of the request, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

D. When a licensee or registrant is required pursuant to 12VAC5-481-1100 , 12VAC5-481-1110 , or 12VAC5-481-1120 to report to the agency any exposure of an individual to sources of radiation, the licensee or the registrant shall also provide the individual a written report on the exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the agency.

E. At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material, during the current year, each licensee or registrant shall provide at termination to each such worker, or to the worker's

designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

12VAC5-481-2290. Presence of Representatives of Licensees or Registrants and Workers During Inspection.

A. Each licensee or registrant shall afford to the agency at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these regulations.

B. During an inspection, agency inspectors may consult privately with workers as specified in 12VAC5-481-2300 . The licensee or registrant may accompany agency inspectors during other phases of an inspection.

C. If, at the time of inspection, an individual has been authorized by the workers to represent them during agency inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

D. Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in 12VAC5-481-2270 .

E. Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

F. With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany agency inspectors during the inspection of physical working conditions.

G. Notwithstanding the other provisions of 12VAC5-481-2290 , agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the United States government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

12VAC5-481-2300. Consultation with Workers During Inspections.

A. Agency inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of these regulations

and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

B. During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition that the worker has reason to believe may have contributed to or caused any violation of the Act, these regulations, or license condition, or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of 12VAC5-481-2310 A.

C. The provisions of subsection B of this section shall not be interpreted as authorization to disregard instructions pursuant to 12VAC5-481-2270 .

12VAC5-481-2310. Requests by Workers for Inspections.

A. Any worker or representative of workers believing that a violation of the Act, these regulations, or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the agency. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the agency no later than at the time of inspection except that, upon the request of the worker giving such notice, such worker's name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the agency, except for good cause shown.

B. If, upon receipt of such notice, the agency determines that the complaint meets the requirements set forth in subsection A of this section, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to this section need not be limited to matters referred to in the complaint.

C. No licensee, registrant, or contractor or subcontractor of a licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these regulations or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of such worker or others of any option afforded by this part.

12VAC5-481-2320. Inspections Not Warranted; Informal Review.

A. Do the following:

1. If the agency determines, with respect to a complaint under 12VAC5-481-2310 , that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the agency shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the agency. The agency will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the

complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the agency. The agency will provide the complainant with a copy of such statement by certified mail.

2. Upon the request of the complainant, the agency may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the agency shall affirm, modify, or reverse the determination of the agency and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.

B. If the agency determines that an inspection is not warranted because the requirements of 12VAC5-481-2310 A have not been met, the complainant shall be notified in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of 12VAC5-481-2310 A.

12VAC5-481-2330. Purpose and Scope.

Part XI. Licensing Requirements for Land Disposal of Radioactive Waste

Article 1. Purpose and Scope

A. The regulations in this part establish procedures, criteria, and terms and conditions upon which the agency issues licenses for the land disposal of wastes received from other persons. The requirements of this part are in addition to, and not in substitution for, other applicable requirements of these regulations.

B. The regulations in this part do not apply to disposal of byproduct material as defined in the definition of "byproduct material" in these regulations in quantities greater than 10,000 kilograms containing more than 185 MBq (5 mCi) of radium-226 or disposal of radioactive material as provided for in Part IV (12VAC5-481-600 et seq.) of this chapter.

C. This part establishes procedural requirements and performance objectives applicable to any method of land disposal. It establishes specific technical requirements for near-surface disposal of radioactive waste that involves disposal in the uppermost portion of the earth.

12VAC5-481-2340. License Required.

Article 2. General Regulatory Provisions

A. No person may receive, possess, and dispose of waste received from other persons at a land disposal facility unless authorized by a license issued by the agency pursuant to this part and Part III (12VAC5-481-380 et seq.) of this chapter.

B. Each person shall file an application with the agency pursuant to 12VAC5-481-440 and obtain a license as provided in this part before commencement of construction of a land disposal facility. Failure to comply with this requirement may be grounds for denial of a

license.

12VAC5-481-2350. Content of Application.

In addition to the requirements set forth in 12VAC5-481-450 , an application to receive from others, possess, and dispose of wastes shall consist of general information, specific technical information, institutional information, and financial information as set forth in 12VAC5-481-2360 through 12VAC5-481-2400 .

12VAC5-481-2360. General Information.

The general information shall include each of the following:

1. Identity of the applicant including:

   a. The full name, address, telephone number, and description of the business or occupation of the applicant;

   b. If the applicant is a partnership, the name and address of each partner and the principal location where the partnership does business;

   c. If the applicant is a corporation or an unincorporated association, (i) the state where it is incorporated or organized and the principal location where it does business, and (ii) the names and addresses of its directors and principal officers; and

   d. If the applicant is acting as an agent or representative of another person in filing the application, all information required under this subsection must be supplied with respect to the other person.

2. Qualifications of the applicant:

   a. The organizational structure of the applicant, both offsite and onsite, including a description of lines of authority and assignments of responsibilities, whether in the form of administrative directives, contract provisions, or otherwise;

   b. The technical qualifications, including training and experience, of the applicant and members of the applicant's staff to engage in the proposed activities. Minimum training and experience requirements for personnel filling key positions described in subdivision 2 a of this section must be provided.

   c. A description of the applicant's personnel training program; and

   d. The plan to maintain an adequate complement of trained personnel to carry out waste receipt, handling, and disposal operations in a safe manner.

3. A description of:

   a. The location of the proposed disposal site;

   b. The general character of the proposed activities;

   c. The types and quantities of waste to be received, possessed, and disposed of;

d. Plans for use of the land disposal facility for purposes other than disposal of wastes; and

e. The proposed facilities and equipment.

4. Proposed schedules for construction, receipt of waste, and first emplacement of waste at the proposed land disposal facility.

12VAC5-481-2370. Specific Technical Information.

The specific technical information shall include the following information needed for demonstration that the performance objectives and the applicable technical requirements of this part will be met:

1. A description of the natural and demographic disposal site characteristics as determined by disposal site selection and characterization activities. The description shall include geologic, geochemical, geotechnical, hydrologic, ecologic, archaelogic, meteorologic, climatologic, and biotic features of the disposal site and vicinity.

2. A description of the design features of the land disposal facility and the disposal units. For near-surface disposal, the description shall include those design features related to infiltration of water; integrity of covers for disposal units; structural stability of backfill, wastes, and covers; contact of wastes with standing water; disposal site drainage; disposal site closure and stabilization; elimination to the extent practicable of long-term disposal site maintenance; inadvertent intrusion; occupational exposures; disposal site monitoring; and adequacy of the size of the buffer zone for monitoring and potential mitigative measures.

3. A description of the principal design criteria and their relationship to the performance objectives.

4. A description of the design basis natural events or phenomena and their relationship to the principal design criteria.

5. A description of codes and standards that the applicant has applied to the design and that will apply to construction of the land disposal facilities.

6. A description of the construction and operation of the land disposal facility. The description shall include as a minimum the methods of construction of disposal units; waste emplacement; the procedures for and areas of waste segregation; types of intruder barriers; onsite traffic and drainage systems; survey control program; methods and areas of waste storage; and methods to control surface water and groundwater access to the wastes. The description shall also include a description of the methods to be employed in the handling and disposal of wastes containing chelating agents or other nonradiological substances that might affect meeting the performance objectives of this part.

7. A description of the disposal site closure plan, including those design features that are intended to facilitate disposal site closure and to eliminate the need for ongoing active maintenance.

8. An identification of the known natural resources at the disposal site, whose exploitation could result in inadvertent intrusion into the wastes after removal of active institutional control.

9. A description of the kind, amount, classification and specifications of the radioactive material proposed to be received, possessed, and disposed of at the land disposal facility.

10. A description of the quality control program for the determination of natural disposal site characteristics and for quality control during the design, construction, operation, and closure of the land disposal facility and the receipt, handling, and emplacement of waste. Audits and managerial controls must be included.

11. A description of the radiation safety program for control and monitoring of radioactive effluents to ensure compliance with the performance objective in 12VAC5-481-2490 and occupational radiation exposure to ensure compliance with the requirements of Part IV (12VAC5-481-600 et seq.) of this chapter and to control contamination of personnel, vehicles, equipment, buildings, and the disposal site. Both routine operations and accidents shall be addressed. The program description must include procedures, instrumentation, facilities, and equipment.

12. A description of the environmental monitoring program to provide data to evaluate potential health and environmental impacts and the plan for taking corrective measures if migration is indicated.

13. A description of the administrative procedures that the applicant will apply to control activities at the land disposal facility.

12VAC5-481-2380. Technical Analyses.

The specific technical information shall also include the following analyses needed to demonstrate that the performance objectives of this part will be met:

1. Pathways analyzed in demonstrating protection of the general population from releases of radioactivity shall include air, soil, groundwater, surface water, plant uptake, and exhumation by burrowing animals. The analyses shall clearly identify and differentiate between the roles performed by the natural disposal site characteristics and design features in isolating and segregating the wastes. The analyses shall clearly demonstrate that there is reasonable assurance that the exposures to humans from the release of radioactivity will not exceed the limits set forth in 12VAC5-481-2490 .

2. Analyses of the protection of individuals from inadvertent intrusion shall include demonstration that there is reasonable assurance the waste classification and segregation requirements will be met and that adequate barriers to inadvertent intrusion will be provided.

3. Analyses of the protection of individuals during operations shall include assessments of expected exposures due to routine operations and likely accidents during handling, storage, and disposal of waste. The analyses shall provide reasonable assurance that exposures will be controlled to meet the requirements of Part IV (12VAC5-481-600 et seq.)

of this chapter.

4. Analyses of the long-term stability of the disposal site and the need for ongoing active maintenance after closure shall be based upon analyses of active natural processes such as erosion, mass wasting, slope failure, settlement of wastes and backfill, infiltration through covers over disposal areas and adjacent soils, and surface drainage of the disposal site. The analyses shall provide reasonable assurance that there will not be a need for ongoing active maintenance of the disposal site following closure.

12VAC5-481-2390. Institutional Information.

The institutional information submitted by the applicant shall include:

1. A certification by the federal or state agency that owns the disposal site that the federal or state agency is prepared to accept transfer of the license when the provisions of 12VAC5-481-2460 are met and will assume responsibility for institutional control after site closure and post-closure observation and maintenance.

2. Where the proposed disposal site is on land not owned by the federal or a state government, the applicant shall submit evidence that arrangements have been made for assumption of ownership in fee by the federal or a state agency before the agency issues a license.

12VAC5-481-2400. Financial Information.

The financial information shall be sufficient to demonstrate that the financial qualifications of the applicant are adequate to carry out the activities for which the license is sought and meet other financial assurance requirements of this part.

12VAC5-481-2410. Requirements for Issuance of a License.

A license for the receipt, possession, and disposal of waste containing or contaminated with radioactive material will be issued by the agency upon finding that:

1. The issuance of the license will not constitute an unreasonable risk to the health and safety of the public;

2. The applicant is qualified by reason of training and experience to carry out the disposal operations requested in a manner that protects health and minimizes danger to life or property;

3. The applicant's proposed disposal site, disposal design, land disposal facility operations, including equipment, facilities, and procedures, disposal site closure, and post-closure institutional control are adequate to protect the public health and safety in that they provide reasonable assurance that the general population will be protected from releases of radioactivity as specified in the performance objective in 12VAC5-481-2490;

4. The applicant's proposed disposal site, disposal site design, land disposal facility operations, including equipment, facilities, and procedures, disposal site closure, and post-closure institutional control are adequate to protect the public health and safety in that

they will provide reasonable assurance that individual inadvertent intruders are protected in accordance with the performance objective in 12VAC5-481-2520;

5. The applicant's proposed land disposal facility operations, including equipment, facilities, and procedures, are adequate to protect the public health and safety in that they will provide reasonable assurance that the standards for radiation protection set out in Part IV (12VAC5-481-600 et seq.) of this chapter will be met;

6. The applicant's proposed disposal site, disposal site design, land disposal facility operations, disposal site closure, and post-closure institutional control are adequate to protect the public health and safety in that they will provide reasonable assurance that long-term stability of the disposed waste and the disposal site will be achieved and will eliminate to the extent practicable the need for ongoing active maintenance of the disposal site following closure;

7. The applicant's demonstration provides reasonable assurance that the applicable technical requirements of this part will be met;

8. The applicant's proposal for institutional control provides reasonable assurance that such control will be provided for the length of time found necessary to ensure the findings in subdivisions 3 through 6 of this section and that the institutional control meets the requirements of 12VAC5-481-2580; and

9. The financial or surety arrangements meet the requirements of this part.

12VAC5-481-2420. Conditions of Licenses.

A. A license issued under this part, or any right thereunder, may be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, only if the agency finds, after securing full information, that the transfer is in accordance with the provisions of the Act and gives its consent in writing in the form of a license amendment.

B. The licensee shall submit written statements under oath upon request of the agency, at any time before termination of the license, to enable the agency to determine whether the license should be modified, suspended, or revoked.

C. The license will be terminated only on the full implementation of the final closure plan as approved by the agency, including post-closure observation and maintenance.

D. The licensee shall be subject to the provisions of the Act now or hereafter in effect, and to all rules, regulations, and orders of the agency. The terms and conditions of the license are subject to amendment, revision, or modification, by reason of amendments to, or by reason of rules, regulations, and orders issued in accordance with the terms of the Act.

E. Each person licensed by the agency pursuant to the regulations in this part shall confine possession and use of materials to the locations and purposes authorized in the license.

F. The licensee shall not dispose of waste until the agency has inspected the land disposal facility and has found it to be in conformance with the description, design, and construction

described in the application for a license.

G. The agency may incorporate in any license at the time of issuance, or thereafter, by appropriate rule, regulation or order, additional requirements and conditions with respect to the licensee's receipt, possession, and disposal of waste as it deems appropriate or necessary in order to:

1. Protect health or to minimize danger to life or property;

2. Require reports and the keeping of records, and to provide for inspections of activities under the license that may be necessary or appropriate to effectuate the purposes of the Act and regulations thereunder.

H. The authority to dispose of wastes expires on the date stated in the license. Any expiration date on a license applies only to the above ground activities and to the authority to dispose of waste. Failure to renew the license shall not relieve the licensee of responsibility for implementing site closure, post-closure observation, and transfer of the license to the site owner.

I. Each licensee shall notify the agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

1. The licensee;

2. An entity (as that term is defined in 11 USC § 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

3. An affiliate (as that term is defined in 11 USC § 101(2)) of the licensee.

J. The notification specified in this section shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

12VAC5-481-2430. Application for Renewal or Closure.

A. An application for renewal or an application for closure under 12VAC5-481-2440 must be filed at least 90 days prior to license expiration.

B. Applications for renewal of a license must be filed in accordance with 12VAC5-481-2350 through 12VAC5-481-2400 . Applications for closure must be filed in accordance with 12VAC5-481-2440 .

C. In any case in which a licensee has filed an application in proper form for renewal of a license, the license does not expire until the agency has taken final action on the application for renewal.

D. In determining whether a license will be renewed, the agency will apply the criteria set forth in 12VAC5-481-2410 .

12VAC5-481-2440. Contents of Application for Site Closure and Stabilization.

A. Prior to final closure of the disposal site, or as otherwise directed by the agency, the applicant shall submit an application to amend the license for closure. This closure application shall include a final revision and specific details of the disposal site closure plan included as part of the license application submitted under subdivision 7 of 12VAC5-481-2370 that includes each of the following:

1. Any additional geologic, hydrologic, or other data pertinent to the long-term containment of emplaced wastes obtained during the operational period.

2. The results of tests, experiments, or any other analyses relating to backfill of excavated areas, closure and sealing, waste migration and interaction with emplacement media, or any other tests, experiments, or analysis pertinent to the long-term containment of emplaced waste within the disposal site.

3. Any proposed revision of plans for:

a. Decontamination and/or dismantlement of surface facilities;

b. Backfilling of excavated areas; or

c. Stabilization of the disposal site for post-closure care.

4. Any significant new information regarding the environmental impact of closure activities and long-term performance of the disposal site.

B. Upon review and consideration of an application to amend the license for closure submitted in accordance with subsection A of this section, the agency shall issue an amendment authorizing closure if there is reasonable assurance that the long-term performance objectives of this part will be met.

12VAC5-481-2450. Post-Closure Observation and Maintenance.

The licensee shall observe, monitor, and carry out necessary maintenance and repairs at the disposal site until the site closure is complete and the license is transferred by the agency in accordance with 12VAC5-481-2460 . Responsibility for the disposal site must be maintained by the licensee for five years. A shorter or longer time period for post-closure observation and maintenance may be established and approved as part of the site closure plan, based on site-specific conditions.

12VAC5-481-2460. Transfer of License.

Following closure and the period of post-closure observation and maintenance, the licensee may apply for an amendment to transfer the license to the disposal site owner. The license shall be transferred when the agency finds:

1. That the closure of the disposal site has been made in conformance with the licensee's disposal site closure plan, as amended and approved as part of the license;

2. That reasonable assurance has been provided by the licensee that the performance objectives of this part are met;

3. That any funds and necessary records for care will be transferred to the disposal site owner;

4. That the post-closure monitoring program is operational for implementation by the disposal site owner; and

5. That the federal or state agency that will assume responsibility for institutional control of the disposal site is prepared to assume responsibility and ensure that the institutional requirements found necessary under subdivision 8 of 12VAC5-481-2410 will be met.

12VAC5-481-2470. Termination of License.

A. Following any period of institutional control needed to meet the requirements found necessary under 12VAC5-481-2410 , the licensee may apply for an amendment to terminate the license.

B. This application will be reviewed in accordance with the provisions of 12VAC5-481-450 .

C. A license shall be terminated only when the agency finds:

1. That the institutional control requirements found necessary under 12VAC5-481-2410 8 have been met;

2. That any additional requirements resulting from new information developed during the institutional control period have been met; and

3. That permanent monuments or markers warning against intrusion have been installed.

12VAC5-481-2480. General Requirement.

Article 3. General Performance Objectives

Land disposal facilities shall be sited, designed, operated, closed, and controlled after closure so that reasonable assurance exists that exposures to individuals are within the requirements established in the performance objectives in 12VAC5-481-2490 through 12VAC5-481-2520 .

12VAC5-481-2490. Protection of the General Population from Releases of Radioactivity.

Concentrations of radioactive material that may be released to the general environment in ground water, surface water, air, soil, plants, or animals shall not result in an annual dose exceeding an equivalent of 0.25 mSv (25 mrem) to the whole body, 0.75 mSv (75 mrem) to the thyroid, and 0.25 mSv (25 mrem) to any other organ of any member of the public. Reasonable effort should be made to maintain releases of radioactivity in effluents to the general environment ALARA.

12VAC5-481-2500. Protection of Individuals from Inadvertent Intrusion.

Design, operation, and closure of the land disposal facility shall ensure protection of any individual inadvertently intruding into the disposal site and occupying the site or contacting the waste at any time after active institutional controls over the disposal site are removed.

12VAC5-481-2510. Protection of Individuals During Operations.

Operations at the land disposal facility shall be conducted in compliance with the standards for radiation protection set out in Part IV (12VAC5-481-600 et seq.) of this chapter, except for releases of radioactivity in effluents from the land disposal facility, that shall be governed by 12VAC5-481-2490 . Every reasonable effort should be made to maintain radiation exposures ALARA.

12VAC5-481-2520. Stability of the Disposal Site After Closure.

The disposal facility shall be sited, designed, used, operated, and closed to achieve long-term stability of the disposal site and to eliminate, to the extent practicable, the need for ongoing active maintenance of the disposal site following closure so that only surveillance, monitoring, or minor custodial care are required.

12VAC5-481-2530. Disposal Site Suitability Requirements for Land Disposal.

Article 4. Technical Requirements for Land Disposal Facilities

Disposal site suitability for near-surface disposal. The primary emphasis in disposal site suitability is given to isolation of wastes and to disposal site features that ensure that the long-term performance objectives are met.

1. The disposal site shall be capable of being characterized, modeled, analyzed and monitored.

2. Within the region where the facility is to be located, a disposal site should be selected so that projected population growth and future developments are not likely to affect the ability of the disposal facility to meet the performance objectives of this part.

3. Areas shall be avoided having known natural resources which, if exploited, would result in failure to meet the performance objectives of this part.

4. The disposal site shall be generally well drained and free of areas of flooding or frequent ponding. Waste disposal shall not take place in a 100-year flood plain, coastal high-hazard area or wetland, as defined in federal Executive Order 11988, "Floodplain Management Guidelines."

5. Upstream drainage areas shall be minimized to decrease the amount of runoff which could erode or inundate waste disposal units.

6. The disposal site shall provide sufficient depth to the water table that ground water intrusion, perennial or otherwise, into the waste will not occur. The agency will consider an exception to this requirement to allow disposal below the water table if it can be conclusively shown that disposal site characteristics will result in molecular diffusion being the predominant means of radionuclide movement and the rate of movement will result in the performance objectives being met. In no case will waste disposal be permitted in the zone of fluctuation of the water table.

7. The hydrogeologic unit used for disposal shall not discharge ground water to the surface

within the disposal site.

8. Areas shall be avoided where tectonic processes such as faulting, folding, seismic activity, or vulcanism may occur with such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of this part or may preclude defensible modeling and prediction of long-term impacts.

9. Areas shall be avoided where surface geologic processes such as mass wasting, erosion, slumping, landsliding, or weathering occur with such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of this part, or may preclude defensible modeling and prediction of long-term impacts.

10. The disposal site must not be located where nearby facilities or activities could adversely impact the ability of the site to meet the performance objectives of this part or significantly mask the environmental monitoring program.

12VAC5-481-2540. Disposal Site Design for Land Disposal.

Disposal site design for near-surface disposal.

1. Site design features shall be directed toward long-term isolation and avoidance of the need for continuing active maintenance after site closure.

2. The disposal site design and operation shall be compatible with the disposal site closure and stabilization plan and lead to disposal site closure that provides reasonable assurance that the performance objectives will be met.

3. The disposal site shall be designed to complement and improve, where appropriate, the ability of the disposal site's natural characteristics to assure that the performance objectives will be met.

4. Covers shall be designed to minimize to the extent practicable water infiltration, to direct percolating or surface water away from the disposed waste, and to resist degradation by surface geologic processes and biotic activity.

5. Surface features shall direct surface water drainage away from disposal units at velocities and gradients that will not result in erosion that will require ongoing active maintenance in the future.

6. The disposal site shall be designed to minimize to the extent practicable the contact of water with waste during storage, the contact of standing water with waste during disposal, and the contact of percolating or standing water with wastes after disposal.

12VAC5-481-2550. Land Disposal Facility Operation and Disposal Site Closure.

Near-surface disposal facility operation and disposal site closure.

1. Wastes designated as Class A pursuant to these regulations shall be segregated from other wastes by placing in disposal units which are sufficiently separated from disposal

units for the other waste classes so that any interaction between Class A wastes and other wastes will not result in the failure to meet the performance objectives of this part. This segregation is not necessary for Class A wastes if they meet the stability requirements of these regulations.

2. Wastes designated as Class C pursuant to these regulations shall be disposed of so that the top of the waste is a minimum of 5 meters below the top surface of the cover or must be disposed of with intruder barriers that are designed to protect against an inadvertent intrusion for at least 500 years.

3. Except as provided in subdivision 12 of this subsection, only waste classified as Class A, B, or C shall be acceptable for near-surface disposal. All waste shall be disposed of in accordance with requirements of 4 through 11 of this subsection.

4. Wastes shall be emplaced in a manner that maintains the package integrity during emplacement, minimizes the void spaces between packages, and permits the void spaces to be filled.

5. Void spaces between waste packages shall be filled with earth or other material to reduce future subsidence within the fill.

6. Waste shall be placed and covered in a manner that limits the radiation dose rate at the surface of the cover to levels that at a minimum will permit the licensee to comply with all provisions of 12VAC5-481-640 at the time the license is transferred pursuant to 12VAC5-481-2460 .

7. The boundaries and locations of each disposal unit shall be accurately located and mapped by means of a land survey. Near-surface disposal units shall be marked in such a way that the boundaries of each unit can be easily defined. Three permanent survey marker control points, referenced to United States Geological Survey (USGS) or National Geodetic Survey (NGS) survey control stations, shall be established on the site to facilitate surveys. The USGS or NGS control stations shall provide horizontal and vertical controls as checked against USGS or NGS record files.

8. A buffer zone of land shall be maintained between any buried waste and the disposal site boundary and beneath the disposed waste. The buffer zone shall be of adequate dimensions to carry out environmental monitoring activities specified in 12VAC5-481-2560 C and take mitigative measures if needed.

9. Closure and stabilization measures as set forth in the approved site closure plan shall be carried out as each disposal unit is filled and covered.

10. Active waste disposal operations shall not have an adverse effect on completed closure and stabilization measures.

11. Only wastes containing or contaminated with radioactive material shall be disposed of at the disposal site.

12. Proposals for disposal of waste that is not generally acceptable for near-surface

disposal because the waste form and disposal methods must be different and, in general, more stringent than those specified for Class C waste, may be submitted to the agency for approval.

12VAC5-481-2560. Environmental Monitoring.

A. At the time a license application is submitted, the applicant shall have conducted a preoperational monitoring program to provide basic environmental data on the disposal site characteristics. The applicant shall obtain information about the ecology, meteorology, climate, hydrology, geology including geophysics and geotechnical engineering, geochemistry, and seismology of the disposal site. For those characteristics that are subject to seasonal variation, data must cover at least a 12-month period.

B. During the land disposal facility site construction and operation, the licensee shall maintain an environmental monitoring program. Measurements and observations must be made and recorded to provide data to evaluate the potential health and environmental impacts during both the construction and the operation of the facility and to enable the evaluation of long-term effects and the need for mitigative measures. The monitoring system must be capable of providing early warning of releases of waste from the disposal site before they leave the site boundary.

C. After the disposal site is closed, the licensee responsible for post-operational surveillance of the disposal site shall maintain a monitoring system based on the operating history and the closure and stabilization of the disposal site. The monitoring system must be capable of providing early warning of releases of waste from the disposal site before they leave the site boundary.

D. The licensee shall have plans for taking corrective measures if the environmental monitoring program detects migration of waste which would indicate that the performance objectives may not be met.

12VAC5-481-2570. Alternative Requirements for Design and Operations.

The agency may, upon request or on its own initiative, authorize provisions other than those set forth in 12VAC5-481-2540 through 12VAC5-481-2560 for the segregation and disposal of waste and for the design and operation of a land disposal facility on a specific basis, if it finds reasonable assurance of compliance with the performance objectives of this part.

12VAC5-481-2571. Waste Classification.

A. Considerations. Determination of the classification of radioactive waste involves two considerations. First, consideration must be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration must be given to the concentration of shorter-lived radionuclides for which

requirements on institutional controls, waste form, and disposal methods are effective.

B. Classes of waste.

1. Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste must meet the minimum requirements set forth in 12VAC5-481-2572 A. If Class A waste also meets the stability requirements set forth in 12VAC5-481-2572 B, it is not necessary to segregate the waste for disposal.

2. Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in 12VAC5-481-2572 .

3. Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth 12VAC5-481-2572 .

4. Waste that is not generally acceptable for near-surface disposal is waste for which form and disposal methods must be different, and in general more stringent, than those specified for Class C waste. In the absence of specific requirements in this part, such waste must be disposed of in a geologic repository as defined in 10 CFR Part 60 or 63 unless proposals for disposal of such waste in a disposal site licensed pursuant to this part are approved by the agency.

C. Classification determined by long-lived radionuclides. If radioactive waste contains only radionuclides listed in Table 2, classification shall be determined as follows:

1. If the concentration does not exceed 0.1 times the value in Table 2, the waste is Class A.

2. If the concentration exceeds 0.1 times the value in Table 2 but does not exceed the value in Table 3, the waste is Class C.

3. If the concentration exceeds the value in Table 2, the waste is not generally acceptable for near-surface disposal.

4. For wastes containing mixtures of radionuclides listed in Table 2, the total concentration shall be determined by the sum of fractions rule described in subsection G of this section.

Table 2
Long Lived Radionuclides Waste Concentration

Radionuclide	Concentration curies per cubic meter
C-14	8
C-14 in activated metal	80
Ni-59 in activated metal	220

Nb-94 in activated metal	0.2
Tc-99	3
I-129	0.08
Alpha emitting transuranic nuclides with half-life greater than 5 years	[1]100
Pu-241	[1]3,500
Cm-242	[1]20,000

[1]Units are nanocuries per gram.

D. Classification determined by short-lived radionuclides. If radioactive waste does not contain any of the radionuclides listed in Table 2, classification shall be determined based on the concentrations shown in Table 3. However, as specified in subsection F of this section, if radioactive waste does not contain any nuclides listed in either Table 2 or 3, it is Class A.

1. If the concentration does not exceed the value in Column 1, the waste is Class A.

2. If the concentration exceeds the value in Column 1, but does not exceed the value in Column 2, the waste is Class B.

3. If the concentration exceeds the value in Column 2, but does not exceed the value in Column 3, the waste is Class C.

4. If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.

5. For wastes containing mixtures of the nuclides listed in Table 3, the total concentration shall be determined by the sum of fractions rule described in subsection G of this section.

Table 3
Short Lived Radionuclide Waste Concentration

Radionuclide	Concentration, curies per cubic meter		
	Col. 1	Col. 2	Col. 3
Total of all nuclides with less than 5 year half-life	700	(1)	(1)
H-3	40	(1)	(1)
Co-60	700	(1)	(1)
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7000

Sr-90	0.04	150	7000
Cs-137	1	44	4600

[1]There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other nuclides in Table 3 determine the waste to the Class C independent of these nuclides.

E. Classification determined by both long- and short-lived radionuclides. If radioactive waste contains a mixture of radionuclides, some of which are listed in Table 2, and some of which are listed in Table 3, classification shall be determined as follows:

1. If the concentration of a nuclide listed in Table 2 does not exceed 0.1 times the value listed in Table 2, the class shall be that determined by the concentration of nuclides listed in Table 3.

2. If the concentration of a nuclide listed in Table 2 exceeds 0.1 times the value listed in Table 2 but does not exceed the value in Table 2, the waste shall be Class C, provided the concentration of nuclides listed in Table 3 does not exceed the value shown in Column 3 of Table 3.

F. Classification of wastes with radionuclides other than those listed in Tables 2 and 3. If radioactive waste does not contain any nuclides listed in either Table 2 or 3, it is Class A.

G. The sum of the fractions rule for mixtures of radionuclides. For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each nuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than 1.0 if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 50 Ci/m^3 and Cs-137 in a concentration of 22 Ci/m^3. Since the concentrations both exceed the values in Column 1, Table 2, they must be compared to Column 2 values. For Sr-90 fraction 50/150=0.33; for Cs-137 fraction, 22/44=0.5; the sum of the fractions=0.83. Since the sum is less than 1.0, the waste is Class B.

H. Determination of concentrations in wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors that relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as nanocuries per gram.

12VAC5-481-2572. Waste Characteristics.

A. The following requirements are minimum requirements for all classes of waste and are

intended to facilitate handling at the disposal site and provide protection of health and safety of personnel at the disposal site.

1. Waste must not be packaged for disposal in cardboard or fiberboard boxes.

2. Liquid waste must be solidified or packaged in sufficient absorbent material to absorb twice the volume of the liquid.

3. Solid waste containing liquid shall contain as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1.0% of the volume.

4. Waste must not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

5. Waste must not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with subdivision 7 of this subsection.

6. Waste must not be pyrophoric. Pyrophoric materials contained in waste shall be treated, prepared, and packaged to be nonflammable.

7. Waste in a gaseous form must be packaged at a pressure that does not exceed 1.5 atmospheres at 20°C. Total activity must not exceed 100 curies per container.

8. Waste containing hazardous, biological, pathogenic, or infectious material must be treated to reduce to the maximum extent practicable the potential hazard from the nonradiological materials.

B. The requirements in this section are intended to provide stability of the waste. Stability is intended to ensure that the waste does not structurally degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

1. Waste must have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

2. Notwithstanding the provisions in subdivision A 2 and A 3 of this section, liquid wastes, or wastes containing liquid, must be converted into a form that contains as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1.0% of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5% of the volume of the waste for waste processed to a stable form.

3. Void spaces within the waste and between the waste and its package must be reduced to the extent practicable.

12VAC5-481-2573. Labeling.

Each package of waste must be clearly labeled to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with 12VAC5-481-2571 .

12VAC5-481-2580. Institutional Requirements.

A. Land ownership. Disposal of waste received from other persons may be permitted only on land owned in fee by the federal or a state government.

B. Institutional control. The land owner or custodial agency shall conduct an institutional control program to physically control access to the disposal site following transfer of control of the disposal site from the disposal site operator. The institutional control program shall also include, but not be limited to, conducting an environmental monitoring program at the disposal site, periodic surveillance, minor custodial care, and other requirements as determined by the agency; and administration of funds to cover the costs for these activities. The period of institutional controls will be determined by the agency, but institutional controls may not be relied upon for more than 100 years following transfer of control of the disposal site to the owner.

12VAC5-481-2590. Alternative Requirements for Waste Classification and Characteristics.

The agency licensing a low-level disposal facility may, upon request or on its own initiative, authorize other provisions for the classification and characteristics of waste on a specific basis, if, after evaluation of the specific characteristics of the waste, disposal site, method of disposal, it finds reasonable assurance of compliance with the performance objectives specified in this part.

12VAC5-481-2600. Applicant Qualifications and Assurances.

Article 5. Financial Assurances

Each applicant shall show that it either possesses the necessary funds or has reasonable assurance of obtaining the necessary funds, or by a combination of the two, to cover the estimated costs of conducting all licensed activities over the planned operating life of the project, including costs of construction and disposal.

12VAC5-481-2610. Funding for Disposal Site Closure and Stabilization.

A. The applicant shall provide assurances prior to the commencement of operations that sufficient funds will be available to carry out disposal site closure and stabilization, including: (i) decontamination or dismantlement of land disposal facility structures; and (ii) closure and stabilization of the disposal site so that following transfer of the disposal site to the site owner the need for ongoing active maintenance is eliminated to the extent

practicable and only minor custodial care, surveillance, and monitoring are required. These assurances shall be based on agency-approved cost estimates reflecting the agency-approved plan for disposal site closure and stabilization. The applicant's cost estimates must take into account total costs that would be incurred if an independent contractor were hired to perform the closure and stabilization work.

B. In order to avoid unnecessary duplication and expense, the agency will accept financial sureties that have been consolidated with earmarked financial or surety arrangements established to meet requirements of federal or other state agencies (and/or local governmental bodies) for such decontamination, closure, and stabilization. The agency will accept these arrangements only if they are considered adequate to satisfy the requirements of this section and that the portion of the surety that covers the closure of the disposal site is clearly identified and committed for use in accomplishing these activities.

C. The licensee's financial or surety arrangement shall be submitted annually for review by the agency to assure that sufficient funds will be available for completion of the closure plan.

D. The amount of the licensee's financial or surety arrangement shall change in accordance with changes in the predicted costs of closure and stabilization. Factors affecting closure and stabilization cost estimates include inflation, increases in the amount of disturbed land, changes in engineering plans, closure and stabilization that has already been accomplished, and any other conditions affecting costs. The financial or surety arrangement shall be sufficient at all times to cover the costs of closure and stabilization of the disposal units that are expected to be used before the next license renewal.

E. The financial or surety arrangement shall be either open-ended or be written for a specified period of time and shall be automatically renewed unless the person who issues the surety notifies the agency, the beneficiary (the site owner), and the principal (the licensee) not less than 90 days prior to the renewal date of its intention not to renew. In such a situation, the licensee must submit a replacement surety within 30 days after notification of cancellation. If the licensee fails to provide a replacement surety acceptable to the agency, the beneficiary may collect on the original surety.

F. Proof of forfeiture shall not be necessary to collect the surety so that, in the event that the licensee could not provide an acceptable replacement surety within the required time, the surety shall be automatically collected prior to its expiration. The conditions described above shall be clearly stated on any surety instrument.

G. Financial or surety arrangements generally acceptable to the agency include surety bonds, cash deposits, certificates of deposit, deposits of government securities, escrow accounts, irrevocable letters or lines of credit, trust funds, and combinations of the above or such other types of arrangements as may be approved by the agency. Self-insurance, or any arrangement that essentially constitutes self-insurance, will not satisfy the surety requirement for private sector applicants.

H. The licensee's financial or surety arrangement shall remain in effect until the closure and stabilization program has been completed and approved by the agency, and the license has been transferred to the site owner.

12VAC5-481-2620. Financial Assurances for Institutional Controls.

A. Prior to the issuance of the license, the applicant shall provide for agency approval, a binding arrangement, between the applicant and the disposal site owner that ensures that sufficient funds will be available to cover the costs of monitoring and any required maintenance during the institutional control period. The binding arrangement shall be reviewed periodically by the agency to ensure that changes in inflation, technology, and disposal facility operations are reflected in the arrangements.

B. Subsequent changes to the binding arrangement specified in subsection A of this section relevant to institutional control shall be submitted to the agency for prior approval.

12VAC5-481-2630. Maintenance of Records, Reports, and Transfers.

Article 6. Records, Reports, Tests, and Inspections

A. Each licensee shall maintain any records and make any reports in connection with the licensed activities as may be required by the conditions of the license or by the rules, regulations, and orders of the agency.

B. Records that are required by these regulations or by license conditions shall be maintained for a period specified by the appropriate regulations or by license condition. If a retention period is not otherwise specified, these records must be maintained and transferred to the officials specified in subsection D of this section as a condition of license termination unless the agency otherwise authorizes their disposition.

C. Records that shall be maintained pursuant to this part may be the original or a reproduced copy or microfilm if this reproduced copy or microfilm is capable of producing copy that is clear and legible at the end of the required retention period.

D. Notwithstanding subsections A through C of this section, copies of records of the location and the quantity of wastes contained in the disposal site must be transferred upon license termination to the chief executive of the nearest municipality, the chief executive of the county in which the facility is located, the county zoning board or land development and planning agency, the state governor, and other state, local and federal governmental agencies as designated by the agency at the time of license termination.

E. Following receipt and acceptance of a shipment of waste, the licensee shall record the date of disposal of the waste, the location in the disposal site, the condition of the waste packages as received, any discrepancies between materials listed on the manifest and those received, and any evidence of leaking or damaged packages or radiation or contamination levels in excess of limits specified in United States Department of Transportation and agency regulations. The licensee shall briefly describe any repackaging operations of any of the waste packages included in the shipment, plus any other information required by the agency as a license condition.

F. Each licensee authorized to dispose of waste received from other persons shall file a copy of its financial report or a certified financial statement annually with the agency in order to update the information base for determining financial qualifications.

G. Do the following:

1. Each licensee authorized to dispose of waste received from other persons, pursuant to this part, shall submit annual reports to the agency. Reports shall be submitted by the end of the first calendar quarter of each year for the preceding year.

2. The reports shall include:

a. Specification of the quantity of each of the principal contaminants released to unrestricted areas in liquid and in airborne effluents during the preceding year,

b. The results of the environmental monitoring program,

c. A summary of licensee disposal unit survey and maintenance activities,

d. A summary, by waste class, of activities and quantities of radionuclides disposed of,

e. Any instances in which observed site characteristics were significantly different from those described in the application for a license, and

f. Any other information the agency may require.

3. If the quantities of waste released during the reporting period, monitoring results, or maintenance performed are significantly different from those predicted, the report must cover this specifically.

12VAC5-481-2640. Tests on Land Disposal Facilities.

Each licensee shall perform, or permit the agency to perform, any tests the agency deems appropriate or necessary for the administration of the regulations in this part, including, but not limited to, tests of:

1. Wastes;

2. Facilities used for the receipt, storage, treatment, handling or disposal of wastes;

3. Radiation detection and monitoring instruments;

4. Other equipment and devices used in connection with the receipt, possession, handling, treatment, storage, or disposal of waste; or

5. Environmental sampling or testing.

12VAC5-481-2650. Agency Inspections of Land Disposal Facilities.

A. Each licensee shall afford to the agency at all reasonable times opportunity to inspect waste not yet disposed of, and the premises, equipment, operations, and facilities in which wastes are received, possessed, handled, treated, stored, or disposed of.

B. Each licensee shall make available to the agency for inspection, upon reasonable notice, records kept by it pursuant to these regulations. Authorized representatives of the agency may copy and take away copies of, for the agency's use, any record required to be kept pursuant to these regulations.

12VAC5-481-2660. Purpose and Scope.

Part XII. Licensing and Radiation Safety Requirements for Irradiators

Article 1. Purpose and Scope

A. This part contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This part also contains radiation safety requirements for operating irradiators. The requirements of this part are in addition to other requirements of this chapter. In particular, the provisions of Parts III (12VAC5-481-380 , et seq.), IV (12VAC5-481-600 , et seq.), X (12VAC5-481-2250 et seq.), and XIII (12VAC5-481-2950 , et seq.) of this chapter apply to applications and licenses subject to this part. Nothing in this part relieves licensees from complying with other applicable federal, state, and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

B. This part applies to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are underwater. Irradiators whose dose rates exceed 500 rad (5 gray) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this part.

C. This part does not apply to self-contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiators.

12VAC5-481-2670. Application for a Specific License.

Article 2. Specific Licensing Requirements

A person, as defined in 12VAC5-481-10 , may file an application for a specific license authorizing the use of sealed sources in an irradiator. Each application shall be sent to the agency along with the appropriate fee prescribed in 12VAC5-490 .

12VAC5-481-2680. Specific Licenses for Irradiators.

A. The agency will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in subsection B of this section and includes the information, as appropriate, from subsections C through I of this section.

B. The applicant shall satisfy the general requirements specified in 12VAC5-481-450 and the requirements contained in this part.

C. The application shall describe the training provided to the irradiator operators including:

1. Classroom training;

2. On-the-job training or simulator training;

3. Safety reviews;

4. Means employed by the applicant to test each operator's understanding of the agency regulations and licensing requirements and the irradiator operating and emergency procedures; and

5. Minimum training and experience of personnel who may provide training.

D. The application shall include the outline of the written operating and emergency procedures listed in the 12VAC5-481-2840 that describes the radiation safety aspects of the procedures.

E. The application shall describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities. In particular, the application shall specify who, within the management structure, has the authority to stop unsafe operations. The application shall also describe the training and experience required for the position of radiation safety officer.

F. The application shall include a description of the access control systems required by 12VAC5-481-2730 , the radiation monitors required by 12VAC5-481-2760 , the method of detecting leaking sources required by 12VAC5-481-2870 including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

G. If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the agency. The description shall include:

1. Instruments to be used;

2. Methods of performing the analysis; and

3. Pertinent experience of the individual who analyzes the samples.

H. If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading shall be done by an organization specifically licensed by the agency, NRC, or another agreement state to load or unload irradiator sources.

I. The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by 12VAC5-481-2880 .

12VAC5-481-2690. Commencement of Construction.

Commencement of construction of a new irradiator may occur prior to the submission to the agency of both an application for a license for the irradiator and the fee required by 12VAC5-490 . Any activities undertaken prior to the issuance of a license are entirely at the risk of the

applicant and have no bearing on the issuance of a license. Commencement of construction, as defined in 12VAC5-481-10 , may include non-construction activities if the activity has a reasonable nexus to radiological safety and security.

12VAC5-481-2700. Applications for Exemptions.

A. The agency may, upon application of any interested person or upon its own initiative, grant any exemptions from the requirements in this part that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

B. Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements in this part. The agency will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that it is likely to provide an adequate level of safety for workers and the public.

12VAC5-481-2710. Request for Written Statements.

A. After the filing of an application, the agency may request further information necessary to enable the agency to determine whether the application shall be granted or denied.

B. Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the agency's request, submit written statements to enable the agency to determine whether the license shall be modified, suspended, or revoked.

12VAC5-481-2720. Performance Criteria for Sealed Sources.

Article 3. Design and Performance Requirements for Irradiators

A. Sealed sources installed after July 1, 1993, shall:

1. Have a certificate of registration issued by the NRC or another agreement state;

2. Be doubly encapsulated;

3. Use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;

4. Be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and

5. In prototype testing of the sealed source, have been leak tested and found leak-free after each of the tests described in subsections B through G of this section.

B. The test source shall be held at -40°C for 20 minutes, 600°C for one hour, then be subjected to a thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds.

C. The test source shall be twice subjected for at least five minutes to an external pressure (absolute) of 2 million newtons per square meter.

D. A 2-kilogram steel weight (2.5. centimeters in diameter) shall be dropped from a height of 1 meter onto the test source.

E. The test source shall be subjected three times for 10 minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of five times the acceleration of gravity. In addition, each test source shall be vibrated for 30 minutes at each resonant frequency found.

F. A 50-gram weight and a pin (0.3 centimeter pin diameter) shall be dropped from a height of 1 meter onto the test source.

G. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source shall be subjected to a force of 2000 newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

12VAC5-481-2730. Access Control.

A. Each entrance to a radiation room at a panoramic irradiator shall have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It shall not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed shall cause the sources to return promptly to their shielded position. The personnel entrance door or barrier shall have a lock that is operated by the same key used to move the sources. The doors and barriers shall not prevent any individual in the radiation room from leaving.

B. In addition, each entrance to a radiation room at a panoramic irradiator shall have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed shall cause the sources to return to their fully shielded position and shall also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm shall also alert at least one other individual who is onsite of the entry. That individual shall be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

C. A radiation monitor shall be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor shall be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels, shall activate the alarm described in subsection B of this section. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.

D. Before the sources move from their shielded position in a panoramic irradiator, the source control shall automatically activate conspicuous visible and audible alarms to alert personnel in the radiation room that the sources will be moved from their shielded position. The alarms

shall give individuals enough time to leave the room before the sources leave the shielded position.

E. Each radiation room at a panoramic irradiator shall have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.

F. Each radiation room of a panoramic irradiator shall contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

G. Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator shall be posted as required by 12VAC5-481-860 . Radiation postings for panoramic irradiators shall comply with the posting requirements of 12VAC5-481-860 , except that signs may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

H. If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it shall not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

I. Underwater irradiators shall have a personnel access barrier around the pool which shall be locked to prevent access when the irradiator is not attended. Only operators and facility management may have access to keys to the personnel access barrier. There shall be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm shall alert an individual (not necessarily on site) who is prepared to respond or summon assistance.

12VAC5-481-2740. Shielding.

A. The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 2 mrem (0.02 mSv) per hour at any location 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate shall be averaged over an area not to exceed 100 square cm having no linear dimension greater than 20 centimeters. Areas where the radiation dose rate exceeds 2 mrem (0.02 mSv) per hour shall be locked, roped off, or posted.

B. The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 2 mrem (0.02 mSv) per hour when the sources are in the fully shielded position.

C. The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator may not exceed 2 mrem (0.02 mSv) per hour and at 5 centimeters from the shield may not exceed 20 mrem (0.2 mSv) per hour.

12VAC5-481-2750. Fire Protection.

A. The radiation room at panoramic irradiator shall have heat and smoke detectors. The

detectors shall activate an audible alarm. The alarm shall be capable of alerting a person who is prepared to summon assistance promptly. The sources shall automatically become fully shielded if a fire is detected.

B. The radiation room at a panoramic irradiator shall be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room shall have a shut-off valve to control flooding into unrestricted areas.

12VAC5-481-2760. Radiation Monitors.

A. Irradiators with automatic product conveyor systems shall have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm shall sound and product conveyors shall stop automatically. The alarm shall be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from this requirement.

B. Underwater irradiators that are not in a shielded radiation room shall have a radiation monitor over the pool to detect abnormal radiation levels. The monitor shall have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The alarm shall be capable of alerting an individual who is prepared to respond promptly.

12VAC5-481-2770. Control of Source Movement.

A. The mechanism that moves the sources of a panoramic irradiator shall require a key to actuate. Actuation of the mechanism shall cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key shall be attached to a portable radiation survey meter by a chain or cable. The lock for source control shall be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room shall require the same key.

B. The console of a panoramic irradiator shall have source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.

C. The control console of a panoramic irradiator shall have a control that promptly returns the sources to the shielded position.

D. Each control for a panoramic irradiator shall be clearly marked as to its function.

12VAC5-481-2780. Irradiator Pools.

A. For licenses initially issued after July 1, 1993, irradiator pools shall have a method to safely store the sources during repairs of the pool and either:

1. Have a watertight stainless steel liner or a liner metallurgically compatible with other components in the pools; or

2. Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination.

B. For licenses initially issued after July 1, 1993, irradiator pools shall have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons shall have siphon breakers to prevent siphoning of pool water.

C. A means shall be provided to replenish water losses from the pool.

D. A visible indicator shall be provided in a clearly visible location to indicate if the pool water level is below the normal low water level or above the normal high water level.

E. Irradiator pools shall be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly.

F. A physical barrier, such as a railing or cover, shall be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

G. If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools may not exceed 2 mrem (0.02 mSv) per hour.

12VAC5-481-2790. Source Rack Protection.

If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack shall be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

12VAC5-481-2800. Power Failures.

A. If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources shall automatically return to the shielded position.

B. The lock on the door of the radiation room of a panoramic irradiator may not be deactivated by a power failure.

C. During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

12VAC5-481-2810. Design Requirements.

A. For all irradiators, licensees shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by 12VAC5-481-2760 A. Licensees shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person.

B. For panoramic irradiators:

1. Licensees shall design shielding walls to meet generally accepted building code

requirements for reinforced concrete and design the walls, wall penetrations, and entrance ways to meet the radiation shielding requirements of 12VAC5-481-2740 . If the irradiator will use more than 5 million curies (2×10^{17} Bq) of activity, licensees shall evaluate the effects of heating of the shielding walls by the irradiator sources.

2. Licensees shall design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.

3. Licensees shall verify from the design and logic diagram that the access control system will meet the requirements of 12VAC5-481-2730 .

4. Licensees shall verify that the number, locations, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. Licensees shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

5. Licensees shall verify that the source rack will automatically return to the fully shielded position if offsite power is lost for more than 10 seconds.

6. Licensees shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

7. Licensees shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources.

8. Licensees shall review the design of the mechanism that moves the sources to assure that the likelihood of a struck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

9. For panoramic irradiators to be built in seismic areas, licensees shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source or local building codes, if current.

D. For pool irradiators:

1. Licensees shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of 12VAC5-481-2780 C, and that metal components are metallurgically compatible with other components in the pool.

2. Licensees shall verify that the design of the water purification system is adequate to meet the requirements of 12VAC5-481-2780 E. The system shall be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

3. Licensees shall verify that there are no crevices on the source or between the source and

the source holders that would promote corrosion on a critical area of the source.

4. If licensees use radiation monitors to detect contamination under 12VAC5-481-2870 B, they shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

12VAC5-481-2820. Construction Monitoring and Acceptance Testing.

A. For all irradiators, licensees shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by 12VAC5-481-2760 A.

B. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in 12VAC5-481-2790 are met for protection of the source rack and the mechanism that moves the rack; testing shall include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.

C. For panoramic irradiators:

1. Licensees shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

2. Licensees shall monitor the construction of the foundations to verify that their construction meets design specifications.

3. Licensees shall test the movement of the source racks for proper operation prior to source loading; testing shall include source rack lowering due to simulated loss of power.

4. Licensees shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

5. Licensees shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. Licensees shall test the operability of the fire extinguishing system.

6. Licensees shall demonstrate that the source racks can be returned to their fully shielded positions without offsite power.

7. For panoramic irradiators that use a computer system to control the access control system, licensees shall verify that the access control system will operate properly if offsite power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

8. Licensees shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

D. For pool irradiators:

1. Licensees shall verify that the pool meets design specifications and shall test the integrity of the pool. Licensees shall verify that outlets and pipes meet the requirements of 12VAC5-481-2780 B.

2. Licensees shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

3. Licensees shall verify the proper operation of the radiation monitors and the related alarm if used to meet 12VAC5-481-2870 B.

E. For underwater irradiators, licensees shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by 12VAC5-481-2760 B.

12VAC5-481-2830. Training.

Article 4. Operation of Irradiators

A. Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall be instructed in:

1. The fundamentals of radiation protection applied to irradiators, including the differences between external radiation and radioactive contamination, units of radiation dose, agency dose limits, why large radiation doses shall be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator;

2. The requirements of Part X (12VAC5-481-2250 et seq.) and Part XII (12VAC5-481-2660 et seq.) of this chapter that are relevant to the irradiator;

3. The operation of the irradiator;

4. Those operating and emergency procedures listed in 12VAC5-481-2840 that the individual is responsible for performing; and

5. Case histories of accidents or problems involving irradiators.

B. Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

C. Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that the individual is to perform.

D. Licensees shall conduct safety reviews for irradiator operators at least annually. Licensees shall give each operator a brief written test on the information. Each safety review shall

include, to the extent appropriate, each of the following:

1. Changes in operating and emergency procedures since the last review;

2. Changes in regulations and license conditions since the last review;

3. Reports on recent accidents, mistakes, or problems that have occurred at irradiators;

4. Relevant results of inspections of operator safety performance;

5. Relevant results of the facility's inspection and maintenance checks; and

6. A drill to practice an emergency or abnormal event procedure.

E. Licensees shall evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating and emergency procedures are followed. Licensees shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct mistakes or deficiencies observed.

F. Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators or for the radiation safety officer, shall be instructed and tested in precautions they shall take to avoid radiation exposure, procedures or parts of procedures listed in 12VAC5-481-2840 that they are expected to perform or comply with, and their proper response to alarms required in this part. Tests may be oral.

G. Individuals who shall be prepared to respond to alarms required by 12VAC5-481-2730 B and I, 12VAC5-481-2750 A, 12VAC5-481-2760 , and 12VAC5-481-2870 B shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests may be oral.

12VAC5-481-2840. Operating and Emergency Procedures.

A. Licensees shall have and follow written operating procedures for:

1. Operation of the irradiator, including entering and leaving the radiation room;

2. Use of personnel dosimeters;

3. Surveying the shielding of panoramic irradiators;

4. Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;

5. Leak testing of sources;

6. Inspection and maintenance checks required by 12VAC5-481-2880 ;

7. Loading, unloading, and repositioning sources if the operations will be performed by the licensee; and

8. Inspection of movable shielding required by 12VAC5-481-2730 , if applicable.

B. Licensees shall have and follow written emergency or abnormal event procedures appropriate for the irradiator type for:

1. Sources stuck in the unshielded position;

2. Personnel overexposures;

3. A radiation alarm from the product exit portal monitor or pool monitor;

4. Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;

5. A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;

6. A prolonged loss of electrical power;

7. A fire alarm or explosion in the radiation room;

8. An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;

9. Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and

10. The jamming of automatic conveyor systems.

C. Licensees may revise operating and emergency procedures without agency approval only if all of the following conditions are met:

1. The revisions do not reduce the safety of the facility;

2. The revisions are consistent with the outline or summary of procedures submitted with the license application;

3. The revisions have been reviewed and approved by the radiation safety officer; and

4. The users or operators are instructed and tested on the revised procedures before they are put into use.

12VAC5-481-2850. Personnel Monitoring.

A. Irradiator operators shall wear a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter processor shall be accredited for the high energy photons in the normal and accident dose ranges (see 12VAC5-481-750). Each personnel dosimeter shall be assigned to and worn by only one individual. Film badges shall be processed at least monthly, and other personnel dosimeters shall be processed at least quarterly.

B. Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who

enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this subsection, a check of their response to radiation shall be done at least annually. Acceptable dosimeters shall read within plus or minus 30% of the true radiation dose.

12VAC5-481-2860. Radiation Surveys.

A. A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator shall be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators shall be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding shall be performed at intervals not to exceed three years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.

B. If the radiation levels specified in 12VAC5-481-2740 are exceeded, the facility shall be modified to comply with the requirements in 12VAC5-481-2740 .

C. Portable radiation survey meters shall be calibrated at least annually to an accuracy of plus or minus 20% for the gamma energy of the sources in use. The calibration shall be done at two points on each scale or for digital instruments at one point per decade over the range that will be used. Portable radiation survey meters shall be of a type that does not saturate and read zero at high radiation dose rates.

D. Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming shall be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations shall not exceed those specified in Table 2, Column 2 or Table 3 of Appendix B to 10 CFR Part 20.

E. Before releasing resins for unrestricted use, they shall be monitored in an area with a background level less than 0.05 mrem (0.5 µSv) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used shall be capable of detecting radiation levels of 0.05 mrem (0.5 µSv) per hour.

12VAC5-481-2870. Detection of Leaking Sources.

A. Each dry-source-storage sealed source shall be tested for leakage at intervals not to exceed six months using a leak test kit or method approved by the agency, NRC, or another agreement state. In the absence of a certificate from a transferor that a test has been made within the six months before the transfer, the sealed source may not be used until tested. The test shall be capable of detecting the presence of 0.005 µCi (200 Bq) of radioactive material and shall be performed by a person approved by the agency, the NRC, or another agreement state to perform the test.

B. For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that a leak test has been done within the six months before the transfer. Water from the pool shall be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor

on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis shall be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels shall activate an alarm. The alarm set-point shall be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

C. If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by an agency, the NRC, or another agreement state licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination shall be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by an agency, the NRC, or another agreement state licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table 2, Column 2 of Appendix B to 10 CFR Part 20. (See 12VAC5-481-1110 for reporting requirements.)

12VAC5-481-2880. Inspection and Maintenance.

A. Licensees shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

1. Operability of each aspect of the access control system required by 12VAC5-481-2730 ;

2. Functioning of the source position indicator required by 12VAC5-481-2770 B;

3. Operability of the radiation monitor for radioactive contamination in pool water required by 12VAC5-481-2870 B using a radiation check source, if applicable;

4. Operability of the over-pool radiation monitor at underwater irradiators as required by 12VAC5-481-2760 B;

5. Operability of the product exit monitor required by 12VAC5-481-2760 A;

6. Operability of the emergency source return control required by 12VAC5-481-2770 C;

7. Leak-tightness of systems through which pool water circulates (visual inspection);

8. Operability of the heat and smoke detectors and extinguisher system required by 12VAC5-481-2750 (but without turning extinguishers on);

9. Operability of the means of pool water replenishment required by 12VAC5-481-2780 C;

10. Operability of the indicators of high and low pool water levels required by 12VAC5-481-2780 D;

11. Operability of the intrusion alarm required by 12VAC5-481-2730 I, if applicable;

12. Functioning and wear of the system, mechanisms, and cables used to raise and lower sources;

13. Condition of the barrier to prevent products from hitting the sources or source mechanism as required by 12VAC5-481-2790;

14. Amount of water added to the pool to determine if the pool is leaking;

15. Electrical wiring on required safety systems for radiation damage; and

16. Pool water conductivity measurements and analysis as required by 12VAC5-481-2890 B.

B. Malfunctions and defects found during inspection and maintenance checks shall be repaired without undue delay.

12VAC5-481-2890. Pool Water Purity.

A. Pool water purification system shall be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, licensees shall take prompt actions to lower pool water conductivity and shall take corrective actions to prevent future recurrences.

B. Licensees shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters shall be calibrated at least annually.

12VAC5-481-2900. Attendance During Operation.

A. Both an irradiator operator and at least one other individual who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds shall be present on site:

1. Whenever the irradiator is operated using an automatic product conveyor system; and

2. Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

B. At a panoramic irradiator at which static irradiations (no movement of the product) are occurring, a person who has received the training on how to respond to alarms described in 12VAC5-481-2830 G shall be on site.

C. At an underwater irradiator, an irradiator operator shall be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they shall have received the training described in 12VAC5-481-2830 F and G. Static

irradiations may be performed without a person present at the facility.

12VAC5-481-2910. Entering and Leaving the Radiation Room.

A. Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to the fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

B. Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:

1. Visually inspect the entire radiation room to verify that no one else is in it; and

2. Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

C. During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by 12VAC5-481-2760 B is operating with backup power.

12VAC5-481-2920. Irradiation of Explosive or Flammable Materials.

A. Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the agency. Authorization will not be granted unless the licensee can demonstrate that denotation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures to personnel.

B. Irradiation of more than small quantities of flammable material (flash point below 140ºF) is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the agency. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures to personnel.

12VAC5-481-2930. Records and Retention Periods.

Article 5. Records

Licensees shall maintain the following records at the irradiator for the periods specified:

1. A copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the agency terminates the license for documents not superseded.

2. Records of each individual's training, tests, and safety reviews provided to meet the requirements of 12VAC5-481-2830 until three years after the individual terminates work.

3. Records of the annual evaluations of the safety performance of irradiator operators required by 12VAC5-481-2830 E for three years after the evaluations.

4. A copy of the current operating and emergency procedures required by 12VAC5-481-2840 until superseded or the agency terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by 12VAC5-481-2840 C retained for three years from the date of the change.

5. Evaluations of personnel dosimeters required by 12VAC5-481-2850 until the agency terminates the license.

6. Records of radiation surveys required by 12VAC5-481-2860 for three years from the date of the survey.

7. Records of radiation survey meter calibrations required by 12VAC5-481-2860 and pool water conductivity meter calibrations required by 12VAC5-481-2890 B until three years from the date of calibration.

8. Records of the results of leak tests required by 12VAC5-481-2870 A and the results of contamination checks required by 12VAC5-481-2870 B for three years from the date of each test.

9. Records of inspection and maintenance checks required by 12VAC5-481-2880 for three years.

10. Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for three years after repairs are completed.

11. Records of receipt, transfer, and disposal, of all licensed sealed sources as required by 12VAC5-481-571 and 12VAC5-481-3100 .

12. Records on the design checks required by 12VAC5-481-2810 and the construction control checks as required by 12VAC5-481-2820 until the license is terminated. The records shall be signed and dated. The title or qualification of the person signing shall be included.

13. Records related to decommissioning of the irradiator as required by 12VAC5-481-450 C.

12VAC5-481-2940. Reports.

A. In addition to the reporting requirements in this chapter, licensees shall report the following events:

1. Source stuck in an unshielded position;

2. Any fire or explosion in a radiation room;

3. Damage to the source racks;

4. Failure of the cable or drive mechanism used to move the source racks;

5. Inoperability of the access control system;

6. Detection of radiation source by the product exit monitor;

7. Detection of radioactive contamination attributable to licensed radioactive material;

8. Structural damage to the pool liner or walls;

9. Abnormal water loss or leakage from the source storage pool (greater than the design parameters); and

10. Pool water conductivity exceeding 100 microsiemens per centimeter.

B. The reports shall include a telephone report within 24 hours as described in 12VAC5-481-1100 and a written report within 30 days as described in 12VAC5-481-1110 .

12VAC5-481-2950. Purpose and Scope.

Part XIII. Transportation of Radioactive Material

Article 1. Purpose and Scope

The regulations in this part apply to any licensee authorized by specific or general license issued by the agency to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in the agency license, or transports that material on public highways. No provision of this part authorizes possession of licensed material.

12VAC5-481-2960. Requirement for License.

Article 2. General Regulatory Provisions

No person shall transport radioactive material or deliver radioactive material to a carrier for transport except as authorized in a general or specific license issued by the agency or as exempted in 12VAC5-481-2970 .

12VAC5-481-2970. Exemptions.

A. Common and contract carriers, freight forwarders, and warehouse workers that are subject to the requirements of the United States Department of Transportation (DOT) in 49 CFR Part 170 through 49 Part CFR 189 or the United States Postal Service in the Postal Service Domestic Mail Manual (DMM), Section C-023.9.0, and the United States Postal Service, are exempt from the requirements of this part to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers that are not subject to the requirements of the DOT or United States Postal Service are subject to 12VAC5-481-2960 and other applicable requirements of these regulations.

B. A licensee is exempt from all the requirements of this part with respect to shipment or carriage of the following low-level materials:

1. NARM and ores containing naturally occurring radionuclides that are not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed 10 times the values specified in Table A-2 of 12VAC5-481-3770 .

2. Materials for which the activity concentration is not greater than the activity concentration values specified in Table A-2 of 12VAC5-481-3770 , or for which the consignment activity is not greater than the limit for an exempt consignment found in Table A-2 of 12VAC5-481-3770 .

C. Fissile material meeting one of the following requirements are exempt from classification as fissile material and from the fissile material package standards of 10 CFR 71.55 and 71.59, but are subject to all other requirements of 10 CFR 71, except as noted.

1. Individual package containing two grams or less fissile material.

2. Individual or bulk packaging containing 15 grams or less of fissile material provided the package has at least 200 grams of solid nonfissile material for every gram of fissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass for solid nonfissile material.

3. Low concentrations of solid fissile material commingled with solid nonfissile material, provided that there is at least 2,000 grams of solid nonfissile material for every gram of fissile material, and there is no more than 180 grams of fissile material distributed within 360 kg of contiguous nonfissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass of solid nonfissile material.

4. Uranium enriched in uranium-235 to a maximum of 1.0% by weight, and with total plutonium and uranium-233 content of up to 1.0% of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than 5.0% of the uranium mass.

5. Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of 2.0% by mass, with a total plutonium and uranium-233 content not exceeding 0.002% of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of 2. The material must be contained in at least a DOT Type A package.

6. Packages containing, individually, a total plutonium mass of not more than 1,000 grams, of which not more than 20% by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

D. Any physician licensed by the Commonwealth of Virginia to dispense drugs in the practice of medicine is exempt from this section with respect to transport by the physician of radioactive material for use in the practice of medicine provided the physician is an authorized user under Part VII (12VAC5-481-1660 et seq.).

12VAC5-481-2980. Transportation of Licensed Material.

A. Each licensee who transports licensed material outside the site of usage, as specified in the agency license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall:

1. Comply with the applicable requirements, appropriate to the mode of transport, of the regulations of the DOT; particularly the regulations of the DOT in the following areas:

a. Packaging – 49 CFR Part 173: Subparts A and B and I.

b. Marking and labeling – 49 CFR Part 172: Subpart D, 172.400 through 172.407 and 172.436 through 172.441.

c. Placarding – 49 CFR Part 172: Subpart F, especially §§ 172.500 through 172.519, 172.556, and Appendices B and C.

d. Accident reporting – 49 CFR Part 171: §§ 171.15 and 171.16.

e. Shipping papers and emergency information – 49 CFR Part 172: Subpart C and Subpart G.

f. Hazardous material employee training – 49 CFR Part 172: Subpart H.

g. Hazardous material shipper/carrier registration – 49 CFR Part 107: Subpart G.

h. Security plans – 49 CFR Part 172: Subpart I.

2. The licensee shall also comply with applicable DOT regulations pertaining to the following modes of transportation:

a. Rail – 49 CFR Part 174: Subparts A through D and K.

b. Air – 49 CFR Part 175.

c. Vessel – 49 CFR Part 176: Subparts A through F and M.

d. Public Highway – 49 CFR Part 177 and Parts 390 through 397.

3. Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee in accordance with 12VAC5-481-900 .

B. If, for any reason, the regulations of the DOT are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of 49 CFR Parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport to the same extent as if the shipment was subject to the regulations.

12VAC5-481-2990. General Licenses for Carriers.

Article 3. General Licenses

A. A general license is hereby issued to any common or contract carrier not exempt under 12VAC5-481-2970 to receive, possess, transport, and store radioactive material in the regular course of their carriage for others or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the United States Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Notification of an incident shall be filed with, or made to, the agency as

prescribed in 49 CFR, regardless of or in addition to notification made to the United States Department of Transportation or other agencies.

B. A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the United States Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Notification of an incident shall be filed with, or made to, the agency as prescribed in 49 CFR, regardless of or in addition to notification made to the United States Department of Transportation or other agencies.

C. Persons who transport radioactive material pursuant to the general licenses in subsection A or B of this section are exempt from the requirements of Parts IV (12VAC5-481-600 et seq.) and X (12VAC5-481-2250 et seq.) of this chapter to the extent that they transport radioactive material.

12VAC5-481-3000. General License: Nrc-Approved Packages.

A. A general license is hereby issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance (CoC), or other approval has been issued by the NRC.

B. This general license applies only to a licensee who:

1. Has a copy of the specific license, CoC, or other approval by the NRC of the package and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;

2. Complies with the terms and conditions of the license, certificate, or other approval by the NRC, as applicable, and the applicable requirements of Part XIII (12VAC5-481-2950 et seq.) of this chapter;

3. Prior to the licensee's first use of the package, submits in writing to the NRC the licensee's name and license number and the package identification number specified in the package approval using the appropriate method listed in 10 CFR 71.1(a); and

4. Has a quality assurance program that complies with 12VAC5-481-3130 .

C. The general license in subsection A of this section applies only when the package approval authorizes use of the package under this general license.

D. For a Type B or fissile material package, the design of which was approved by the NRC before April 1, 1996, the general license is subject to the additional restrictions of 12VAC5-481-3010 .

12VAC5-481-3010. Previously Approved Packages.

A Type B(U) package, a Type B(M) package or a fissile material package, previously approved by the NRC but without the designation "-85" in the identification number of the NRC CoC, may be used under the general license of 12VAC5-481-3000 with the following additional

conditions:

1. Fabrication of the package is satisfactorily completed by April 1, 1999, as demonstrated by application of its model number in accordance with 10 CFR 71.85(c);

2. A package used for a shipment to a location outside the United States is subject to multilateral approval except approved under special arrangement in accordance with United States Department of Transportation regulations at 49 CFR 173.403; and

3. A serial number that uniquely identifies each packaging that conforms to the approved design is assigned to and legibly and durably marked on the outside of each packaging.

12VAC5-481-3020. General License: United States Department of Transportation Specification Container.

A. A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a specification container for fissile material or for a Type B quantity of radioactive material as specified in 49 CFR Parts 173 and 178.

B. This general license applies only to a licensee who:

1. Has a copy of the specification;

2. Complies with the terms and conditions of the specification and the applicable requirements of this part; and

3. Has a quality assurance program that complies with 12VAC5-481-3130 .

C. The general license in subsection A of this section is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States except by multilateral approval as defined in 49 CFR 173.403.

12VAC5-481-3030. General License: Use of Foreign Approved Package.

A. A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate that has been revalidated by the DOT as meeting the applicable requirements of 49 CFR 171.12.

B. This general license applies only to international shipments.

C. This general license applies only to a licensee who:

1. Has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;

2. Complies with the terms and conditions of the certificate and revalidation, and with the applicable requirements of this part; and

3. The licensee has a quality assurance program that complies with 12VAC5-481-3130 .

12VAC5-481-3040. General License: Fissile Material.

A. A general license is issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this section. The fissile material need not be contained in a package that meets the standards of 10 CFR Part 71, Subparts E and F; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

B. The general license applies only to a licensee who has a quality assurance program that complies with 12VAC5-481-3130 .

C. The general license applies only when a package's contents:

1. Contain no more than a Type A quantity of radioactive material; and

2. Contain less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.

D. The general license applies only to packages containing fissile material that are labeled with a CSI that:

1. Has been determined in accordance with subsection E of this section;

2. Has a value less than or equal to 10; and

3. For a shipment of multiple packages containing fissile material, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

E. The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$CSI = 10\left[\frac{grams\ of\ {}^{235}U}{X} + \frac{gram\ of\ {}^{233}U}{Y} + \frac{grams\ of\ Pu}{Z}\right]$$

1. The calculated CSI must be rounded up to the first decimal place;

2. The values of X, Y, and Z used in the CSI equation must be taken from Tables 5 or 6, as appropriate;

3. If Table 5 is used to obtain the value of X, then the values for the terms in the equation for uranium-233 and plutonium must be assumed to be zero; and

4. Table 4 values for X, Y, and Z must be used to determine the CSI if:

a. Uranium-233 is present in the package;

b. The mass of plutonium exceeds one percent of the mass of uranium-235;

c. The uranium is of unknown uranium-235 enrichment or greater than 24 weight percent enrichment; or

d. Substances having a moderating effectiveness (i.e., an average hydrogen density greater than H_2O) (e.g., certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.

Table 4
Mass Limits for General License Packages Containing Mixed Quantities of Fissile Material or Uranium-235 of Unknown Enrichment

Fissile material	Fissile material mass mixed with moderating substances having an average hydrogen density less than or equal to H_2O (grams)	Fissile material mass mixed with moderating substances having an average hydrogen density greater than H_2O[a] (grams)
U-235 (X)	60	38
U-233 (Y)	43	27
Pu-239 or Pu-241 (Z)	37	24

[a]When mixtures of moderating substances are present, the lower mass limits shall be used if more than 15 percent of the moderating substance has an average hydrogen density greater than H_2O.

Table 5
Mass Limits for General License Packages Containing Uranium-235 of Known Enrichment

Uranium enrichment in weight percent of U-235 not exceeding	Fissile material mass of U-235 (X) (grams)
24	60
20	63
15	67
11	72
10	76
9.5	78
9	81
8.5	82
8	85
7.5	88
7	90

6.5	93
6	97
5.5	102
5	108
4.5	114
4	120
3.5	132
3	150
2.5	180
2	246
1.5	408
1.35	480
1	1,020
0.92	1,800

12VAC5-481-3050. (Repealed.)

12VAC5-481-3051. General License: Plutonium-Berylium Special Form Material.

A. A general license is issued to any licensee to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped in accordance with this section. This material need not be contained in a package that meets the standards of Subparts E and F of 10 CFR Part 71; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

B. The general license applies only to a licensee who has a quality assurance program that complies with 12VAC5-481-3130 .

C. The general license applies only when a package's contents:

1. Contain no more than a Type A quantity of radioactive material; and

2. Contain less than 1,000 grams of plutonium, provided that: plutonium-239, plutonium-241, or any combination of these radionuclides, constitutes less than 240 grams of the total quantity of plutonium in the package.

D. The general license applies only to packages labeled with a CSI that:

1. Has been determined in accordance with subsection E of this section;

2. Has a value less than or equal to 100; and

3. For a shipment of multiple packages containing Pu-Be sealed sources, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

E. The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$CSI = 10\left[\frac{\text{grams of Pu-239} + \text{grams of Pu-241}}{24}\right]$$

The calculated CSI must be rounded up to the first decimal place.

12VAC5-481-3060. Assumptions As to Unknown Properties of Fissile Material.

Article 4. Operating Controls and Procedures

When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

12VAC5-481-3070. Preliminary Determinations.

Prior to the first use of any packaging for the shipment of radioactive material:

1. The licensee shall ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects which could significantly reduce the effectiveness of the packaging;

2. Where the maximum normal operating pressure will exceed 35 kilopascal (5 lbf/in^2) gauge, the licensee shall test the containment system at an internal pressure at least 50% higher than the maximum normal operating pressure to verify the capability of that system to maintain its structural integrity at that pressure;

3. The licensee shall determine that the packaging has been fabricated in accordance with the design approved by the NRC; and

4. The licensee shall conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number as assigned by the NRC.

12VAC5-481-3080. Routine Determinations.

Prior to each shipment of licensed material, the licensee shall determine that:

1. The package is proper for the contents to be shipped;

2. The package is in unimpaired physical condition except for superficial defects such as marks or dents;

3. Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

4. Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

5. Any pressure relief device is operable and set in accordance with written procedures;

6. The package has been loaded and closed in accordance with written procedures;

7. For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;

8. Any structural part of the package that could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements specified in 10 CFR 71.45;

9. The level of nonfixed radioactive contamination on the external surfaces of each package offered for shipment is ALARA and within the limits specified in 49 CFR 173.443;

10. External radiation levels around the package and around the vehicle, if applicable, will not exceed the limits specified in 10 CFR 71.47 at any time during transportation; and

11. Accessible package surface temperatures will not exceed the limits specified in 10 CFR 71.43(g) at any time during transportation.

12VAC5-481-3090. Air Transport of Plutonium.

Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this part or included indirectly by citation of the DOT regulations, as may be applicable, the licensee shall assure that plutonium in any form is not transported by air, or delivered to a carrier for air transport, unless:

1. The plutonium is contained in a medical device designed for individual human application;

2. The plutonium is contained in a material in which the specific activity is less than or equal to the activity concentration values for plutonium specified in Table A-2 of 12VAC5-481-3770 and in which the radioactivity is essentially uniformly distributed;

3. The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form and is shipped in accordance with 12VAC5-481-2980;

4. The plutonium is shipped in a package specifically authorized, in the CoC, issued by the NRC, for the shipment of plutonium by air and the licensee requires, through special arrangement with the carrier, compliance with 49 CFR 175.704, the DOT regulations applicable to the air transport of plutonium.

12VAC5-481-3091. Opening Instructions.

Before delivery of a package to a carrier for transport, the licensee shall ensure that any

special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with 12VAC5-481-900 .

12VAC5-481-3100. Shipment Records.

Each licensee shall maintain for a period of three years after shipment a record of each shipment of licensed material not exempt under 12VAC5-481-2970 , showing, where applicable:

1. Identification of the packaging by model number and serial number;

2. Verification that the packaging, as shipped, had no significant defect;

3. Volume and identification of coolant;

4. Type and quantity of licensed material in each package, and the total quantity of each shipment;

5. Date of the shipment;

6. Name and address of the transferee;

7. Address to which the shipment was made; and

8. Results of the determinations required by 12VAC5-481-3080 and by the conditions of the package approval.

12VAC5-481-3110. Reports.

The licensee shall report to the agency within 30 days:

1. Any instance in which there is significant reduction in the effectiveness of any packaging during use;

2. Details of any defects with safety significance in the packaging after first use, with the means employed to repair the defects and prevent their recurrence; or

3. Instances in which the conditions of approval in the CoC were not observed in making a shipment.

12VAC5-481-3120. Advance Notification of Transport of Nuclear Waste.

A. Prior to the transport of any nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee shall provide advance notification of such transport.

B. Advance notification for transport of licensed material is required when:

1. The licensed material is required to be in Type B packaging for transportation;

2. The licensed material is being transported to or across state boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and

3. The quantity of licensed material in a single package exceeds:

a. 3000 times the A_1 value of the radionuclides as specified in 12VAC5-481-3770;

b. 3000 times the A_2 value of the radionuclides as specified in 12VAC5-481-3770; or

c. 1000 terabecquerel (27,000 curies).

C. Each advance notification required by subsections A and B of this section shall contain the following information:

1. The name, address, and telephone number of the shipper, carrier, and receiver of the shipment;

2. A description of the nuclear waste contained in the shipment as required by 49 CFR 172.202 and 172.203(d);

3. The point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;

4. The seven-day period during which arrival of the shipment at state boundaries or tribal reservation boundaries is estimated to occur;

5. The destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and

6. A point of contact with a telephone number for current shipment information.

D. The notification required by subsections A and B of this section shall be made in writing to each office of the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and to the agency. A notification delivered by mail shall be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A notification delivered by any other means than mail shall reach each office of the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and the agency, at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for three years.

1. A list of names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the Federal Register on June 30, 1995 (60 FR 34306).

2. Contact information for each state, including telephone and mailing addresses of governors and governors' designees, and participating tribes, including telephone and mailing addresses of tribal officials and tribal officials' designees, is available on the NRC website at: https://scp.nrc.gov/special/designee.pdf .

3. A list of the names and mailing addresses of the governors' designees and tribal officials' designees of participating tribes is available on request from the Director, Division of Material Safety, State, Tribal and Rulemaking Program, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

E. The licensee shall notify the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and the agency of any changes to schedule information provided pursuant to subsections A and B of this section. Such notification shall be by telephone to a responsible individual in the office of the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and the agency. The licensee shall maintain for three years a record of the name of the individual contacted.

F. Each licensee who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice, identifying the advance notification that is being canceled, to the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and to the agency. A copy of the notice shall be retained by the licensee for three years.

12VAC5-481-3130. Quality Assurance.

Article 5. Quality Assurance

A. Quality assurance requirements apply to the design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. Quality assurance comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. The licensee, certificate holder, and applicant for a CoC are responsible for the quality assurance requirements as they apply to design, fabrication, testing, and modification of packaging. Each licensee is responsible for the quality assurance provision that applies to its use of packaging for the shipment of licensed material subject to this chapter.-

B. Each licensee, certificate holder and applicant for a CoC shall establish, maintain, and execute a quality assurance program satisfying each of that applicable criteria of this section, 10 CFR Part 71, Subpart H and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee, certificate holder, and applicant for CoC shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

C. Before the use of any package for the shipment of licensed material subject to this rule, each licensee shall obtain NRC approval of its quality assurance program.

D. A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of 12VAC5-481-1270 , is deemed to satisfy the requirements of 12VAC5-481-3000 and subsection B of this section.

E. The licensee, certificate holder, and applicant for a CoC shall be responsible for the establishment and execution of the quality assurance program. The licensee, certificate holder, and applicant for a CoC may delegate to others, such as contractors, agents, or

consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. The licensee shall clearly establish and delineate, in writing, the authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions. While the term licensee is used in these criteria, the requirements are applicable to whatever design, fabrication, assembly, and testing of the package is accomplished with respect to a package before the time a package is issued.

F. The quality assurance functions are:

1. Assuring that an appropriate quality assurance program is established and effectively executed; and

2. Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the safety-related functions have been performed correctly.

G. The persons and organizations performing quality assurance functions must have sufficient authority and organizational freedom to:

1. Identify quality problems;

2. Initiate, recommend, or provide solutions; and

3. Verify implementation of solutions.

12VAC5-481-3140. Purpose.

Part XIV. Radiation Safety Requirements for Wireline Service Operations and Subsurface Tracer Studies

Article 1. Purpose and Scope

The regulations in this part establish radiation safety requirements for using sources of radiation for wireline service operations including mineral-logging, radioactive markers, and subsurface tracer studies. The requirements of this part are in addition to, and not in substitution for, the requirements of Parts I (12VAC5-481-10 et seq.), II (12VAC5-481-260 et seq.), III (12VAC5-481-380 et seq.), IV (12VAC5-481-600 et seq.), and X (12VAC5-481-2250 et seq.) of this chapter.

12VAC5-481-3150. Scope.

The regulations in this part apply to all licensees or registrants who use sources of radiation for wireline service operations including mineral-logging, radioactive markers, or subsurface tracer studies.

12VAC5-481-3151. Licensing.

A. The agency will approve an application for a specific license for the use of licensed

material in well logging if the applicant meets the following requirements:

1. The applicant satisfies the general requirements specified in 12VAC5-481-440 and 12VAC5-481-450 .

2. The applicant shall develop a program for training logging supervisors and logging assistants and submit to the agency a description of this program that specifies:

a. Initial training;

b. On-the-job training;

c. Annual safety reviews provided by the licensee;

d. Means the applicant will use to demonstrate the logging supervisor's knowledge and understanding of and ability to comply with the agency's regulations and licensing requirements and the applicant's operating and emergency procedures; and

e. Means the applicant will use to demonstrate the logging assistant's knowledge and understanding of and ability to comply with the applicant's operating and emergency procedures.

3. The applicant shall submit to the agency written operating and emergency procedures as described in 12VAC5-481-3280 or an outline or summary of the procedures that includes the important radiation safety aspects of the procedures.

4. The applicant shall establish and submit to the agency its program for annual inspections of the job performance of each logging supervisor to ensure that the agency's regulations, license requirements, and the applicant's operating and emergency procedures are followed. Inspection records shall be retained for three years after each annual internal inspection.

5. The applicant shall submit a description of its overall organizational structure as it applies to the radiation safety responsibilities in well logging, including specified delegations of authority and responsibility.

6. If an applicant wants to perform leak testing of sealed sources, the applicant shall identify the manufacturers and the model numbers of the leak test kits to be used. If the applicant wants to analyze its own wipe samples, the applicant shall establish procedures to be followed and submit a description of these procedures to the agency. The description must include the following:

a. Instruments to be used;

b. Methods of performing the analysis; and

c. Pertinent experience of the person who will analyze the wipe samples.

12VAC5-481-3160. Agreement with Well Owner.

Article 2. Prohibition

A. No licensee shall perform wireline service operations with a sealed source(s) unless, prior to commencement of the operation, the licensee has a written agreement with the well operator, well owner, drilling contractor, or land owner that:

1. In the event a sealed source is lodged downhole, a reasonable effort at recovery will be made;

2. No person may attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture;

3. In the event a decision is made to abandon the sealed source downhole, the requirements of 12VAC5-481-3370 C shall be met;

4. The radiation monitoring required in 12VAC5-481-3340 will be performed; and

5. If the environment, any equipment, or personnel are contaminated with licensed material, they must be decontaminated before release from the site or release for unrestricted use.

B. The licensee shall retain a copy of the written agreement for three years after the completion of the well logging operation.

12VAC5-481-3170. Limits on Levels of Radiation.

Article 3. Equipment Control

Sources of radiation shall be used, stored, and transported in such a manner that the transportation requirements of Part XIII (12VAC5-481-2950 et seq.) of this chapter and the dose limitation requirements of Part IV (12VAC5-481-600 et seq.) of this chapter are met.

12VAC5-481-3180. Storage Precautions.

A. Each source of radiation, except accelerators, shall be provided with a storage or transport container. The container shall be provided with a lock, or tamper seal for calibration sources, to prevent unauthorized removal of, or exposure to, the source of radiation.

B. Sources of radiation shall be stored in a manner that will minimize danger from explosion or fire.

12VAC5-481-3190. Transport Precautions.

Transport containers shall be physically secured to the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

12VAC5-481-3200. Radiation Survey Instruments.

A. The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each field station to make physical radiation surveys as required by this part and by Part IV (12VAC5-481-600 et seq.). Instrumentation shall be capable of measuring 0.001 mSv (0.1 mrem) per hour through at least 0.5 mSv (50 mrem) per hour.

B. Each radiation survey instrument shall be calibrated:

1. At intervals not to exceed six months and after each instrument servicing;

2. For linear scale instruments, at two points located approximately 25% and 75% of full-scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two points of at least one decade; and for digital instruments, at appropriate points; and

3. So that accuracy within 20% of the true radiation level can be demonstrated on each scale.

C. Calibration records shall be maintained for a period of three years.

12VAC5-481-3210. Leak Testing of Sealed Sources.

A. Requirements. Each licensee using sealed sources of radioactive material shall have the sources tested for leakage. Records of leak test results shall be kept in units of becquerels (microcuries) and maintained for three years after the leak test is performed.

B. Method of Testing. Tests for leakage shall be performed only by persons specifically authorized to perform such tests by the agency, the NRC, or another agreement state. The test sample shall be taken from the surface of the source, source holder, or from the surface of the device in which the source is stored or mounted and on which one might expect contamination to accumulate. The test sample shall be analyzed for radioactive contamination, and the analysis shall be capable of detecting the presence of 185 Bq (0.0005 µCi) of radioactive material on the test sample.

C. Interval of Testing. Each sealed source (except an energy compensated source (ECS)) shall be tested at intervals not to exceed six months. Each ECS that is not exempt in subsection E of this section must be tested at intervals not to exceed three years. In the absence of a certificate from a transferor indicating that a test has been made prior to the transfer, the sealed source shall not be put into use until tested. If, for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.

D. Leaking or Contaminated Sources. If the test reveals the presence of 185 Bq (0.005 µCi) or more of leakage or contamination, the licensee shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired, or disposed of in accordance with these regulations. The licensee shall check the equipment associated with the leaking source for radioactive contamination and, if contaminated, have it decontaminated or disposed of in accordance with these regulations. A report describing the equipment involved, the test results, and the corrective action taken shall be filed with the agency within five days of receiving the test results.

E. Exemptions. The following sources are exempted from the periodic leak test requirements of subsections A through D of this section:

1. Hydrogen-3 sources;

2. Sources of radioactive material with a half-life of 30 days or less;

3. Sealed sources of radioactive material in gaseous form;

4. Sources of beta- or gamma-emitting radioactive material with an activity of 3.7 MBq (100 µCi) or less; and

5. Sources of alpha-emitting radioactive material with an activity of 0.37 MBq (10 µCi) or less.

12VAC5-481-3220. Physical Inventory.

Each licensee or registrant shall conduct a semi-annual physical inventory to account for all sources of radiation. Records of inventories shall be maintained for three years from the date of the inventory and shall include the quantities and kinds of sources of radiation, the location the date of the inventory, and the name of the individual conducting the inventory.

12VAC5-481-3230. Utilization Records.

Each licensee or registrant shall maintain current records, which shall be kept available for three years from the date of the recorded event, showing the following information for each source of radiation:

1. Make, model number, and a serial number or a description of each source of radiation used;

2. The identity of the well-logging supervisor responsible for the source and the logging assistant present;

3. Locations where used and dates of use; and

4. In the case of tracer materials and radioactive markers, the utilization record shall indicate the radionuclide and activity used in a particular well.

12VAC5-481-3240. Design, Performance, and Certification Criteria for Sealed Sources Used in Downhole Operations.

A. Each sealed source, except those containing radioactive material in gaseous form, and ECSs used in downhole operations, shall meet the following minimum criteria:

1. Be of doubly encapsulated construction;

2. Contain radioactive material whose chemical and physical forms are as insoluble and nondispersible as practical; and

3. Certified by one of the following methods:

a. For a sealed source manufactured on or before July 14,1989, a licensee may use the sealed source, for use in well-logging applications if it meets the requirements of USASI N5.10-1968, "Classification of Sealed Radioactive Sources," or the requirements in subdivision 3 b or c of this subsection;

b. For a sealed source manufactured after July 1989, a licensee may use the sealed

source, for use in well-logging applications if it meets the oil well-logging requirements of ANSI/HPS N43.6-1997, "Sealed Radioactive Sources-Classification"; or

c. For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in well-logging applications, if the sealed source's prototype has been tested and found to maintain its integrity after each of the following tests:

(1) Temperature. The test source must be held at -40°C for 20 minutes, 600°C for 1 hour, and then be subject to a thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds.

(2) Impact test. A 5 kg steel hammer, 2.5 cm in diameter, must be dropped from a height of 1 m onto the test source.

(3) Vibrations test. The test source must be subject to a vibration from 25 Hz to 500 Hz at 5 g amplitude for 30 minutes.

(4) Puncture test. A 1 gram hammer and pin, 0.3 cm pin diameter, must be dropped from a height of 1 m onto the test source.

(5) Pressure test. The test source must be subject to an external pressure of 1.695×10^7 pascals (24,600 pounds per square inch absolute).

B. Certification documents shall be maintained for inspection by the agency for a period of two years after source disposal. If the source is abandoned downhole, the certification documents shall be maintained until the agency authorizes disposition.

C. Energy Compensated Source (ECS). Licensee use of an ECS, which may contain no greater than 3.7 MBq (100 µCi), is exempt from this part, except the following:

1. For well-logging applications with a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of 12VAC5-481-3210 , 12VAC5-481-3220 and 12VAC5-481-3230 .

2. For well-logging applications without a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of 12VAC5-481-3160 , 12VAC5-481-3210 , 12VAC5-481-3220 , 12VAC5-481-3230 , subsection D of this section and 12VAC5-481-3370 .

3. ECSs must be registered with the NRC under 10 CFR 32.210 or with an agreement state.

D. Use of a sealed source in a well without a surface casing. The licensee may use a sealed source in a well without a surface casing for protecting fresh water aquifers only if the licensee follows a procedure for reducing the probability of the source becoming lodged in the well. The procedure must be approved by the agency pursuant to 12VAC5-481-3151 A 3.

12VAC5-481-3241. Tritium Neutron Generator Target Sources.

A. Use of a tritium neutron generator target source, containing quantities not exceeding 1,110 GBq (30 curies) and in a well with a surface casing to protect fresh water aquifers, is subject to the requirements of this part except 12VAC5-481-3160 , 12VAC5-481-3240 and

12VAC5-481-3370 .

B. Use of a tritium neutron generator target source, containing quantities exceeding 1,110 GBq (30 curies) or in a well without a surface casing to protect fresh water aquifers, is subject to the requirements of this part except 12VAC5-481-3240 .

12VAC5-481-3250. Labeling.

A. Each source, source holder, or logging tool containing radioactive material shall bear a durable, legible, and clearly visible marking or label, that has, as a minimum, the standard radiation caution symbol, without the conventional color requirement, and the following wording:

DANGER or CAUTION

RADIOACTIVE MATERIAL

This labeling shall be on the smallest component transported as a separate piece of equipment.

B. Each transport container shall have permanently attached to it a durable, legible, and clearly visible label which has, as a minimum, the standard radiation caution symbol and the following wording:

DANGER or CAUTION

RADIOACTIVE MATERIAL

NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)

C. Uranium sinker bars used in well-logging applications shall be legibly impressed with the following words:

CAUTION

RADIOACTIVE DEPLETED URANIUM

NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY) IF FOUND

12VAC5-481-3260. Inspection and Maintenance.

A. Each licensee shall visually check source holders, logging tools, and source handling tools, for defects before each use to ensure that the equipment is in good working condition and that required labeling is present. If defects are found, the equipment must be removed from service until repaired, and a record must be made listing: the date of check, name of inspector, equipment involved, defects found, and repairs made. These records must be retained for three years after the defect is found.

B. Each licensee or registrant shall conduct, at intervals not to exceed six months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools to assure proper labeling and physical condition. Records of inspection and maintenance shall be maintained for a period

of three years.

C. If any inspection conducted pursuant to subsection B of this section reveals damage to labeling or components critical to radiation safety, the device shall be removed from service until repairs have been made.

D. If a sealed source is stuck in the source holder, the licensee shall not perform any operation, such as drilling, cutting, or chiseling, on the source holder unless the licensee is specifically approved by the agency, NRC, or another agreement state to perform this operation.

E. The repair, opening, or modification of any sealed source shall be performed only by persons specifically authorized to do so by the agency, the NRC, or another agreement state.

12VAC5-481-3261. Radioactive Markers.

The licensee may use radioactive markers in wells only if the individual markers contain quantities of licensed material not exceeding the quantities specified in 12VAC5-481-3730 . The use of markers is subject only to the requirements of 12VAC5-481-3220 .

12VAC5-481-3262. Uranium Sinker Bars.

The licensee may use a uranium sinker bar in well logging applications only if it is legibly impressed with the words "CAUTION -- RADIOACTIVE -- DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES (or COMPANY NAME) IF FOUND."

12VAC5-481-3270. Training Requirements.

Article 4. Requirements for Personal Safety

A. No licensee shall permit any individual to act as a logging supervisor as defined in this part until such individual has:

1. Received instruction in the following and demonstrated an understanding thereof:

    a. Fundamentals of radiation safety including:

    (1) Characteristics of radiation;

    (2) Units of radiation dose and quantity of radioactivity;

    (3) Hazards of exposure to radiation;

    (4) Levels of radiation from licensed material;

    (5) Methods of controlling radiation dose (time, distance, and shielding); and

    (6) Radiation safety practices, including prevention of contamination, and methods of decontamination;

    b. Radiation detection instruments including:

    (1) Use, operation, calibration, and limitations of radiation survey instruments;

(2) Survey techniques; and

(3) Use of personnel monitoring equipment;

c. Equipment to be used including:

(1) Operation of equipment, including source handling equipment and remote handling tools;

(2) Storage, control, and disposal of licensed material; and

(3) Maintenance of equipment;

d. The requirements of pertinent Virginia regulations; and

e. Case histories of accidents in well logging;

2. Received copies of and instruction in the regulations contained in this part and the applicable sections of Parts I (12VAC5-481-10 et seq.), IV (12VAC5-481-600 et seq.), and X (12VAC5-481-2250 et seq.) of this chapter or their equivalent, conditions of appropriate license, and the licensee's operating and emergency procedures, and demonstrated an understanding thereof;

3. Demonstrated competence to use sources of radiation, related handling tools, and radiation survey instruments which will be used on the job by a field evaluation; and

4. Demonstrated understanding of subdivisions 1 and 2 of this subsection by successfully passing a written test.

B. No licensee or registrant shall permit any individual to act as a logging assistant until such individual has:

1. Received instruction in the applicable sections of Parts I (12VAC5-481-10 et seq.), IV (12VAC5-481-600 et seq.) and X (12VAC5-481-2250 et seq.) of this chapter or their equivalent;

2. Received copies of, and instruction in the licensee's operating and emergency procedures;

3. Demonstrated understanding of subdivisions 1 and 2 of this subsection by successfully passing a written or oral test; and

4. Demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools, and radiation survey instruments that will be used on the job.

C. The licensee shall provide safety reviews at least once during each calendar year.

D. The licensee shall maintain employee training records for three years following termination of the individual's employment.

12VAC5-481-3280. Operating and Emergency Procedures.

The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

1. Handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in Part IV (12VAC5-481-600 et seq.) of this chapter;

2. Methods and occasions for conducting radiation surveys;

3. Methods and occasions for locking and securing sources of radiation;

4. Personnel monitoring and the use of personnel monitoring equipment;

5. Transportation to temporary jobsites and field stations, including the packaging and placing of sources of radiation in vehicles, placarding of vehicles, and securing sources of radiation during transportation;

6. Minimizing exposure of individuals in the event of an accident;

7. Procedure for notifying proper personnel in the event of an accident;

8. Maintenance of records;

9. Use, inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools;

10. Procedure to be followed in the event a sealed source is lodged downhole;

11. Procedures to be used for picking up, receiving, and opening packages containing radioactive material;

12. For the use of tracers, decontamination of the environment, equipment, and personnel;

13. Maintenance of records generated by logging personnel at temporary jobsites;

14. Notifying proper persons in the event of an accident; and

15. Actions to be taken if a sealed source is ruptured, including actions to prevent the spread of contamination and minimize inhalation and ingestion of radioactive material and actions to obtain suitable radiation survey instruments as required by 12VAC5-481-3200 .

12VAC5-481-3290. Personnel Monitoring.

A. No licensee shall permit any individual to act as a logging supervisor or a logging assistant unless each such individual wears either a film badge, OSL or TLD. Each film badge, OSL or TLD shall be assigned to and worn by only one individual. Film badges must be replaced at least monthly and OSLs or TLDs replaced at least quarterly. After replacement, each film badge, OSL or TLD must be promptly processed.

B. Personnel monitoring records shall be maintained for inspection until the agency authorizes disposition.

12VAC5-481-3300. Security.

Article 5. Precautionary Procedures in Logging and Subsurface Tracer Studies

A. A logging supervisor must be physically present at a temporary job site whenever licensed materials are being handled or are not stored and locked in a vehicle or storage place. The logging supervisor may leave the job site to obtain assistance if a source becomes lodged in a well.

B. During well logging, except when radiation sources are below ground or in shipping or storage containers, the logging supervisor or other individual designated by the logging supervisor must maintain direct surveillance of the operation to prevent unauthorized entry into a restricted area as defined in 12VAC5-481-10 .

12VAC5-481-3310. Handling Tools.

The licensee shall provide and require the use of tools that will assure remote handling of sealed sources other than low-activity calibration sources.

12VAC5-481-3320. Subsurface Tracer Studies.

A. Protective gloves and other appropriate protective clothing and equipment shall be used by all personnel handling radioactive tracer material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material.

B. No licensee shall cause the injection of radioactive material into potable aquifers without prior written authorization from the agency.

12VAC5-481-3330. Particle Accelerators.

No licensee or registrant shall permit above-ground testing of particle accelerators, designed for use in well-logging, which results in the production of radiation, except in areas or facilities so controlled or shielded that the requirements of 12VAC5-481-630 and 12VAC5-481-640 , as applicable, are met.

12VAC5-481-3340. Radiation Surveys and Contamination Control.

Article 6. Radiation Surveys and Records

A. Radiation surveys or calculations shall be made and recorded for each area where radioactive materials are used and stored.

B. Radiation surveys shall be made and recorded for the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive material. Such surveys shall include each source of radiation or combination of sources to be transported in the vehicle.

C. If the sealed source assembly is removed from the logging tool before departing the jobsite, the logging tool detector shall be energized, or a survey meter used, to assure that the logging tool is free of contamination.

D. Radiation surveys shall be made and recorded at the jobsite or well-head for each tracer operation, except those using hydrogen-3, carbon-14, and sulfur-35. These surveys shall

include measurements of radiation levels before and after the operation.

E. Records required pursuant to subsections A through D of this section shall include the dates, the identification of individual(s) making the survey, the identification of survey instrument(s) used, and an exact description of the location of the survey. Records of these surveys shall be maintained for three years after completion of the survey.

F. If the licensee detects evidence that a sealed source has ruptured or licensed materials have caused contamination, the licensee shall initiate immediately the emergency procedures required by 12VAC5-481-3280 and contact the agency immediately.

G. During efforts to recover a sealed source lodged in the well, the licensee shall continuously monitor, with an appropriate radiation detection instrument or a logging tool with a radiation detector, the circulating fluids from the well, if any, to check for contamination resulting from damage to the sealed source.

H. If contamination results from the use of licensed material in well logging, the licensee shall decontaminate all work area equipment and personnel before release from the site or release for unrestricted use.

12VAC5-481-3350. Documents and Records Required at Field Stations.

Each licensee shall maintain the following documents and records for the specific devices and sources used at the field station:

1. Appropriate license, certificate of registration, or equivalent document(s);

2. Operating and emergency procedures;

3. Copy of Part IV (12VAC5-481-600 et seq.), Part X (12VAC5-481-2250 et seq.) and this part;

4. Records of the latest survey instrument calibrations pursuant to 12VAC5-481-3200;

5. Records of the latest leak test results pursuant to 12VAC5-481-3210;

6. Records of physical inventories required pursuant to 12VAC5-481-3220;

7. Utilization records required pursuant to 12VAC5-481-3230;

8. Records of inspection and maintenance required pursuant to 12VAC5-481-3260;

9. Survey records required pursuant to 12VAC5-481-3340; and

10. Training records required pursuant to 12VAC5-481-3270 .

12VAC5-481-3360. Documents and Records Required at Temporary Jobsites.

Each licensee or registrant conducting operations at a temporary jobsite shall have the following documents and records available at that site for inspection by the agency:

1. Operating and emergency procedures;

2. Survey records required pursuant to 12VAC5-481-3340 for the period of operation at the site;

3. Evidence of current calibration for the radiation survey instruments in use at the site;

4. When operating in the state under reciprocity, a copy of the appropriate license, certificate of registration, or equivalent document(s); and

5. Shipping papers for the transportation of radioactive material.

12VAC5-481-3370. Notification of Incidents, Abandonment, and Lost Sources.

Article 7. Notification

A. Notification of incidents and sources lost in other than downhole logging operations shall be made in accordance with appropriate provisions of Part IV (12VAC5-481-600 et seq.) of this chapter.

B. Whenever a sealed source or device containing radioactive material is lodged downhole, the licensee shall:

1. Monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations; and

2. Notify the agency immediately by telephone and subsequently, within 30 days, by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. This letter shall identify the well or other location, describe the magnitude and extent of the escape of radioactive material, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.

C. When it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall:

1. Advise the well-operator of the regulations of the Virginia Department of Mines, Minerals, and Energy; Division of Gas and Oil, regarding abandonment and an appropriate method of abandonment, that shall include:

a. The immobilization and sealing in place of the radioactive source with a cement plug,

b. The setting of a whipstock or other deflection device, and

c. The mounting of a permanent identification plaque at the surface of the well, containing the appropriate information required by subsection D of this section;

2. Notify the agency by telephone, giving the circumstances of the loss, and request approval of the proposed abandonment procedures; and

3. File a written report with the agency within 30 days of the abandonment. The licensee shall send a copy of the report to the Virginia Department of Mines, Minerals, and Energy; Division of Gas and Oil. The report shall contain the following information:

a. Date of occurrence;

b. A description of the well logging source involved, including the radionuclide and its quantity, chemical, and physical form;

c. Surface location and identification of the well;

d. Results of efforts to immobilize and seal the source in place;

e. A brief description of the attempted recovery effort;

f. Depth of the source;

g. Depth of the top of the cement plug;

h. Depth of the well;

i. Any other information, such as a warning statement, contained on the permanent identification plaque; and

j. The names of state agencies receiving a copy of this report.

D. Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque for posting the well or well-bore. This plaque shall:

1. Be constructed of long-lasting material, such as stainless steel or monel; and

2. Contain the following information engraved on its face:

a. The word "CAUTION";

b. The radiation symbol without the conventional color requirement;

c. The date of abandonment;

d. The name of the well operator or well owner;

e. The well name and well identification number(s) or other designation;

f. The sealed source(s) by radionuclide and activity;

g. The source depth and the depth to the top of the plug; and

h. An appropriate warning, depending on the specific circumstances of each abandonment.

E. The licensee shall immediately notify the agency by telephone and subsequently by confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable aquifer. Such notice shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of such loss, and explain efforts planned or being taken to mitigate these consequences.

12VAC5-481-3380. Purpose and Scope.

Part XV. Therapeutic Radiation Machines

A. This part establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines. The provisions of this part are in addition to, and not in substitution for, other applicable provisions of these regulations.

B. The use of therapeutic radiation machines shall be by, or under the supervision of, a licensed practitioner of the healing arts who meets the training/experience criteria established by 12VAC5-481-3390 C.

12VAC5-481-3390. General Administrative Requirements for Facilities Using Therapeutic Radiation Machines.

A. Administrative controls. The registrant shall be responsible for directing the operation of the therapeutic radiation machines that have been registered with the agency. The registrant or the registrant's agent shall ensure that the requirements of Part XV (12VAC5-481-3380 et seq.) of this chapter are met in the operation of the therapeutic radiation machines.

B. A therapeutic radiation machine that does not meet the provisions of this chapter shall not be used for irradiation of patients.

C. Training for external beam radiation therapy authorized users. The registrant for any therapeutic radiation machine subject to 12VAC5-481-3420 or 12VAC5-481-3430 shall require the authorized user to be a physician who:

1. Is certified in:

   a. Radiation oncology or therapeutic radiology by the American Board of Radiology or radiology (combined diagnostic and therapeutic radiology program) by the American Board of Radiology prior to 1976;

   b. Radiation oncology by the American Osteopathic Board of Radiology;

   c. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

   d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons;

   or

2. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

   a. To satisfy the requirement for instruction, the classroom and laboratory training shall include:

   (1) Radiation physics and instrumentation;

   (2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of ionization radiation; and

(4) Radiation biology.

b. To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include:

(1) Review of the full calibration measurements and periodic quality assurance checks;

(2) Evaluation of prepared treatment plans and calculation of treatment times and patient treatment settings;

(3) Using administrative controls to prevent misadministrations;

(4) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and

(5) Checking and using radiation survey meters.

c. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

(1) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations or contraindications;

(2) Selecting proper dose and how it is to be administered;

(3) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses or treatment plans as warranted by patients' reaction to radiation; and

(4) Post-administration follow-up and review of case histories.

3. Notwithstanding the requirements of subdivisions 1 and 2 of this subsection, the registrant for any therapeutic radiation machine subject to 12VAC5-481-3420 may also submit the training of the prospective authorized user physician for agency review on a case-by-case basis.

4. A physician shall not act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the agency.

D. Training for qualified medical physicist. The registrant for any therapeutic radiation machine subject to 12VAC5-481-3420 and 12VAC5-481-3430 shall require the qualified medical physicist to be registered with the agency, under the provisions of Part II (12VAC5-481-260 et seq.) of this chapter, as a provider of radiation services in the area of calibration

and surveys of external beam radiation therapy units and to:

1. Be certified by the American Board of Radiology in:

   a. Therapeutic radiological physics;

   b. Roentgen-ray and gamma-ray physics;

   c. X-ray and radium physics; or

   d. Radiological physics;

2. Be certified by the American Board of Medical Physics in Radiation Oncology Physics;

3. Be certified by the Canadian College of Medical Physics; or

4. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university and have completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a qualified medical physicist at a medical institution. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy external beam radiation therapy (photons and electrons with energies greater than or equal to one MV/one MeV). To meet this requirement, the individual shall have performed the tasks listed in 12VAC5-481-3400 A, 12VAC5-481-3420 P, 12VAC5-481-3420 Q, 12VAC5-481-3430 T, and 12VAC5-481-3430 U under the supervision of a qualified medical physicist during the year of work experience.

E. Qualifications of operators.

1. Individuals who will be operating a therapeutic radiation machine for medical use shall be American Registry of Radiologic Technologists (ARRT) Registered Radiation Therapy Technologists. Individuals who are not ARRT Registered Radiation Therapy Technologists shall submit evidence that they have satisfactorily completed a radiation therapy technologist training program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology.

2. The names and training of all personnel currently operating a therapeutic radiation machine shall be kept on file at the facility. Information on former operators shall be retained for a period of at least two years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

F. Written safety procedures and rules shall be developed by a qualified medical physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules.

G. Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a therapeutic radiation machine authorized user. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes.

H. Visiting authorized user. Notwithstanding the provisions of subsection G of this section, a registrant may permit any physician to act as a visiting authorized user under the term of the registrant's Certificate of Registration for up to 60 days per calendar year under the following conditions:

1. The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee, where applicable; and

2. The visiting authorized user meets the requirements established for an authorized user in subdivisions C 1 and C 2 of this section; and

3. The registrant shall maintain copies of the written permission required in subdivision 1 of this subsection and documentation that the visiting authorized user met the requirements of subdivision 2 of this subsection for five years from the date of the last visit.

I. All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the registrant's quality management program. In addition to the requirements of Part XV of this chapter, these individuals are also subject to the requirements of 12VAC5-481-640 , 12VAC5-481-680 , and 12VAC5-481-760 .

J. Information and maintenance record and associated information. The registrant shall maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the agency:

1. Report of acceptance testing;

2. Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by Part XV of this chapter, as well as the names of persons who performed such activities;

3. Records of maintenance or modifications performed on the therapeutic radiation machine after September 20, 2006, as well as the names of persons who performed such services;

4. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

K. Records retention. All records required by Part XV of this chapter shall be retained until disposal is authorized by the agency unless another retention period is specifically authorized in Part XV of this chapter. All required records shall be retained in an active file from at least the time of generation until the next agency inspection. Any required record generated prior to the last agency inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as the agency authorizes final disposal.

12VAC5-481-3400. General Technical Requirements for Facilities Using Therapeutic Radiation Machines.

A. Protection surveys.

1. The registrant shall ensure that radiation protection surveys of all new facilities and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with 12VAC5-481-3440 . The radiation protection survey shall be performed by, or under the direction of, a qualified medical physicist or a qualified inspector and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field, and with a scattering phantom in the useful beam of radiation:

a. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 12VAC5-481-640; and

b. Radiation levels in unrestricted areas do not exceed the limits specified in 12VAC5-481-720 .

2. In addition to the requirements of subdivision 1 of this subsection, a radiation protection survey shall also be performed prior to any subsequent medical use and:

a. After making any change in the treatment room shielding;

b. After making any change in the location of the therapeutic radiation machine within the treatment room;

c. After relocating the therapeutic radiation machine; or

d. Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

3. The survey record shall indicate all instances where the facility, in the opinion of the qualified medical physicist or a qualified inspector, is in violation of applicable regulations. The survey record shall also include the date of the measurements, the reason the survey is required, the manufacturer's name, the model number and serial number of the therapeutic radiation machine, the instruments used to measure radiation levels, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microsieverts or millirems per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the individual responsible for conducting the survey;

4. If the results of the surveys required by subdivision 1 or 2 of this subsection indicate any radiation levels in excess of the respective limit specified in subdivision 1 of this subsection, the registrant shall lock the control in the "OFF" position and not use the unit:

a. Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

b. Until the registrant has received a specific exemption from the agency.

B. Modification of radiation therapy unit or room before beginning a treatment program. If the survey required by subsection A of this section indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 12VAC5-481-720 , before beginning the treatment program the registrant shall:

1. Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 12VAC5-481-720;

2. Perform the survey required by subsection A of this section again; and

3. Include in the report required by subsection D of this section the results of the initial survey, a description of the modification made to comply with subdivision 1 of this subsection, and the results of the second survey; or

4. Request and receive a registration amendment under 12VAC5-481-720 that authorizes radiation levels in unrestricted areas greater than those permitted by 12VAC5-481-720 .

C. Dosimetry equipment.

1. The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration. An independent survey shall be conducted by a qualified inspector or qualified medical physicist other than the person performing the original survey prior to the equipment being used except as described in subsection A of this section:

a. For beams with energies greater than one MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60;

b. For beams with energies equal to or less than one MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured;

2. The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with subdivision 1 of this subsection. This comparison shall have been performed within the previous 12 months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in subdivision 1 of this subsection;

3. The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license or registration. For each calibration, intercomparison, or comparison, the record shall include: the date; the model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by subdivisions 1 and 2 of this subsection; the correction factors that were determined; the names of the individuals who performed the calibration, intercomparison, or comparison; and evidence that the intercomparison was performed by,

or under the direct supervision and in the physical presence of, a qualified medical physicist.

D. Reports of external beam radiation therapy surveys and measurements. The registrant for any therapeutic radiation machine subject to 12VAC5-481-3420 or 12VAC5-481-3430 shall furnish a copy of the records required in subsections A and B of this section to the agency within 30 days following completion of the action that initiated the record requirement.

12VAC5-481-3410. Quality Management Program.

Each registrant or applicant subject to 12VAC5-481-3420 and 12VAC5-481-3430 shall develop, implement, and maintain a quality management program to provide high confidence that radiation will be administered as directed by the authorized user.

A. Scope and applicability. The quality management program shall address, at a minimum, the following specific objectives:

1. Written directives.

a. A written directive shall be dated and signed by an authorized user prior to the administration of radiation. If because of the patient's condition a delay caused by providing a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.

b. The written directive shall contain the patient's or human research subject's name, type and energy of the beam, total dose, dose per fraction, treatment site, and number of fractions.

c. A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the therapeutic radiation machine dose or the next fractional dose.

d. The registrant shall retain a copy of the written directive for three years.

2. Procedures for administrations. The registrant shall develop, implement, and maintain written procedures to provide high confidence that:

a. Prior to the administration of each course of radiation treatment, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

b. Each administration is in accordance with the written directive;

c. Therapeutic radiation machine final plans of treatment and related calculations are in accordance with the respective written directives by:

(1) Checking both manual and computer-generated dose calculations to verify they are correct and in accordance with the written directive; and

(2) Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

d. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken; and

e. The registrant retains a copy of the procedures for administrations for the duration of the registration.

B. Reports and notifications of misadministrations.

1. A registrant shall report any event resulting from the treatment of a patient or human research subject in which the administration of therapeutic radiation machine radiation results, or will result in, unintended permanent functional damage to an organ or a physiological system as determined by a physician.

2. Other than events that result from the treatment of a patient or human research subject, a registrant shall report any event in which the administration of a therapeutic radiation machine therapy dose:

a. Involves the wrong patient, wrong treatment modality, or wrong treatment site;

b. The calculated weekly administered dose differs from the weekly prescribed dose by more than 30%; or

c. The calculated total administered dose differs from the total prescribed dose by more than 20% of the total prescribed dose.

3. The registrant shall notify the agency by telephone no later than the next calendar day after the discovery of a misadministration.

4. The registrant shall submit a written report to the agency within 15 days after the discovery of a misadministration. The written report shall include:

a. The registrant's name;

b. The name of the prescribing physician;

c. A brief description of the event;

d. Why the event occurred;

e. The effect, if any, on the individual who received the misadministration;

f. Actions, if any, that have been taken or are planned to prevent recurrence; and

g. Certification that the registrant notified the individual, or the individual's responsible relative or guardian, and if not, why not.

5. The report shall not contain the individual's name or any other information that could lead to the identification of the individual.

6. The registrant shall provide notification of the event to the referring physician and also

notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the registrant shall notify the individual as soon as possible thereafter. The registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this subdivision, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

7. Aside from the notification requirement, nothing in this section affects any rights or duties of registrants and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.

8. The registrant shall retain a record of a misadministration in accordance with subsection C of this section. A copy of the required record shall be provided to the referring physician if other than the registrant within 15 days after discovery of the misadministration.

C. Records of misadministrations. A registrant shall retain a record of misadministrations reported in accordance with subsection B of this section for three years. The record shall contain the following:

1. The registrant's name and the names of the individuals involved;

2. The social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration;

3. A brief description of the event; why it occurred; and the effect, if any, on the individual;

4. The actions, if any, taken or planned to prevent recurrence; and

5. Whether the registrant notified the individual, or the individual's responsible relative or guardian and, if not, whether such failure to notify was based on guidance from the referring physician.

12VAC5-481-3420. Therapeutic Radiation Machines of Less Than 500 Kv.

A. Leakage radiation. When the x-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

1. 550 kV systems. The leakage air kerma rate measured at any position five centimeters from the tube housing assembly shall not exceed one mGy (100 mrad) in any one hour.

2. Greater than 50 and less than 500 kV systems. The leakage air kerma rate measured at a

distance of one meter from the target in any direction shall not exceed one cGy (1 rad) in any one hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of five centimeters from the surface of the tube housing assembly shall not exceed 30 cGy (30 rad) per hour.

3. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in subdivisions 1 and 2 of this subsection for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the agency.

B. Permanent beam limiting devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

C. Adjustable or removable beam limiting devices.

1. All adjustable or removable beam limiting devices, diaphragms, cones or blocks shall not transmit more than 5.0% of the useful beam for the most penetrating beam used;

2. When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

D. Filter system. The filter system shall be so designed that:

1. Filters cannot be accidentally displaced at any possible tube orientation;

2. For equipment installed after September 20, 2006, an interlock system prevents irradiation if the proper filter is not in place;

3. The air kerma rate escaping from the filter slot shall not exceed one cGy (1 rad) per hour at one meter under any operating conditions; and

4. Each filter shall be marked as to its material of construction and its thickness.

E. Tube immobilization.

1. The x-ray tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and

2. The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

F. Source marking. The tube housing assembly shall be so marked that it is possible to determine the location of the source to within five millimeters, and such marking shall be readily accessible for use during calibration procedures.

G. Beam block. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

H. Timer. A suitable irradiation control device shall be provided to terminate the irradiation

after a pre-set time interval.

1. A timer with a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time or time remaining indicator;

2. The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a preselected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

4. The timer shall permit accurate pre-setting and determination of exposure times as short as one second;

5. The timer shall not permit an exposure if set at zero;

6. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

7. The timer shall be accurate to within 1.0% of the selected value or one second, whichever is greater.

I. Control panel functions. The control panel, in addition to the displays required by other provisions in this section, shall have:

1. An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

2. An indication of whether x-rays are being produced;

3. A means for indicating x-ray tube potential and current;

4. The means for terminating an exposure at any time;

5. A locking device which will prevent unauthorized use of the therapeutic radiation machine; and

6. For therapeutic radiation machines manufactured after September 20, 2006, a positive display of specific filters in the beam.

J. Multiple tubes. When a control panel may energize more than one x-ray tube:

1. It shall be possible to activate only one x-ray tube at any time;

2. There shall be an indication at the control panel identifying which x-ray tube is activated; and

3. There shall be an indication at the tube housing assembly when that tube is energized.

K. Target-to-skin distance (TSD). There shall be a means of determining the central axis TSD

to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

L. Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five seconds after the x-ray "ON" switch is energized, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

M. Low filtration x-ray tubes. Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

N. Facility design requirements for therapeutic radiation machines capable of operating in the range 50 kV to 500 kV. In addition to adequate shielding to meet requirements of 12VAC5-481-3450 , the treatment room shall meet the following design requirements:

1. Aural communication. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel;

2. Viewing systems. Provision shall be made to permit continuous observation of the patient during irradiation and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

O. Additional requirements. Treatment rooms that contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

1. All protective barriers shall be fixed except for entrance doors or beam interceptors;

2. The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;

3. Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

4. When any door referred to in subdivision 3 of this subsection is opened while the x-ray tube is activated, the air kerma rate at a distance of one meter from the source shall be reduced to less than one mGy (100 mrad) per hour.

P. Full calibration measurements.

1. Full calibration of a therapeutic radiation machine subject to this section shall be performed by, or under the direct supervision of, a qualified medical physicist:

a. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;

b. At intervals not exceeding one year; and

c. Before medical use under the following conditions:

(1) Whenever quality assurance check measurements indicate that the radiation output differs by more than 5.0% from the value obtained at the last full calibration and the difference cannot be reconciled; and

(2) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

d. Notwithstanding the requirements of subdivision 1 c of this subsection:

(1) Full calibration of therapeutic radiation machines with multienergy capabilities is required only for those modes or energies that are not within their acceptable range; and

(2) If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in subdivision 1 c (1) of this subsection.

2. To satisfy the requirement of subdivision 1 of this subsection, full calibration shall include all measurements recommended for annual calibration by the National Council on Radiation Protection and Measurements (NCRP) Report 69, "Dosimetry of X-ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV" (1981).

3. The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include: the date of the calibration; the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the x-ray tube; the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and the signature of the qualified medical physicist responsible for performing the calibration.

Q. Periodic quality assurance checks.

1. Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to this section, which are capable of operation at greater than or equal to 50 kV;

2. To satisfy the requirement of subdivision 1 of this subsection, quality assurance checks shall meet the following requirements:

a. The registrant shall perform quality assurance checks in accordance with written procedures established by the qualified medical physicist; and

b. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration

specified in subdivision P 1 of this section. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in subdivision P 1 of this section, shall be stated;

3. The cause for a parameter exceeding a tolerance set by the qualified medical physicist shall be investigated and corrected before the system is used for patient irradiation;

4. Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the qualified medical physicist's quality assurance check procedures, the system shall be recalibrated as required in subdivision P 1 of this section;

5. The registrant shall use the dosimetry system described in 12VAC5-481-3400 C 2 to make the quality assurance check required in subdivision 2 of this subsection;

6. The registrant shall have the qualified medical physicist review and sign the results of each radiation output quality assurance check within 30 days of the date that the check was performed;

7. The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to this section are performed at intervals not to exceed 30 days;

8. Notwithstanding the requirements of subdivisions 4 and 7 of this subsection, the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by subdivisions 4 and 7 of this subsection have been performed within the 30-day period immediately prior to said administration;

9. To satisfy the requirement of subdivision 7 of this subsection, safety quality assurance checks shall ensure proper operation of:

a. Electrical interlocks at each external beam radiation therapy room entrance;

b. The "BEAM-ON" and termination switches;

c. Beam condition indicator lights on the access door, control console, and in the radiation therapy room;

d. Viewing systems; and

e. If applicable, electrically operated treatment room doors from inside and outside the treatment room; and

10. The registrant shall maintain a record of each quality assurance check required by subdivisions 1 and 7 of this subsection for three years. The record shall include the date of the quality assurance check; the manufacturer's name, the model number, and serial number of the therapeutic radiation machine; the manufacturer's name, the model number, and serial number for the instruments used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the

periodic quality assurance check.

R. Operating procedures.

1. The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of subsections P and Q of this section have been met;

2. Therapeutic radiation machines shall not be left unattended unless secured pursuant to subdivision I 5 of this section;

3. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

4. The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and an apron of not less than 0.5 millimeters lead equivalency at 100 kV;

5. A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

6. No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of 12VAC5-481-640 .

S. Possession of survey instruments. Each facility location authorized to use a therapeutic radiation machine in accordance with this section shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 µSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instruments shall be operable and calibrated in accordance with 12VAC5-481-3440 .

T. Electronic brachytherapy devices are subject to the requirements of 12VAC5-481-3452 and are exempt from the requirements of this section.

12VAC5-481-3430. Therapeutic Radiation Machines - Photon Therapy Systems (500 Kv and Above) and Electron Therapy Systems (500 Kv and Above).

A. Possession of survey instruments. Each facility location authorized to use a therapeutic radiation machine in accordance with this section shall have access to appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 µSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instruments shall be operable and calibrated in accordance with 12VAC5-481-3440 .

B. Leakage radiation outside the maximum useful beam in photon and electron modes.

1. The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the

maximum sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e., patient plane), shall not exceed a maximum of 0.2% and an average of 0.1% of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane;

2. Except for the area defined in subdivision 1 of this subsection, the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5% of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters;

3. For equipment manufactured after September 20, 2006, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in subdivisions 1, 2, and 3 of this subsection for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the agency.

C. Leakage radiation through beam limiting devices.

1. Photon radiation. All adjustable or interchangeable beam limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting devices shall not exceed 2.0% of the maximum absorbed dose on the central axis of the useful beam measured in a 100 square centimeter radiation field, or maximum available field size if less than 100 square centimeters;

2. Electron radiation. All adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

a. A maximum of 2.0% and average of 0.5% of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and

b. A maximum of 10% of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam.

3. Measurement of leakage radiation.

a. Photon radiation. Measurements of leakage radiation through the beam limiting

devices shall be made with the beam limiting devices closed and any residual aperture blocked by at least two tenth-value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding 10 square centimeters;

b. Electron radiation. Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one centimeter of water equivalent build up material.

D. Filters and wedges.

1. Each wedge filter that is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined.

2. If the absorbed dose rate information required by subsection I of this section relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter shall be removable only by the use of tools.

3. For equipment manufactured after September 20, 2006, that utilizes wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils:

a. Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;

b. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

c. A display shall be provided at the treatment control panel showing the wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils in use; and

d. An interlock shall be provided to prevent irradiation if any filter or beam scattering foil selection operation carried out in the treatment room does not agree with the filter or beam scattering foil selection operation carried out at the treatment control panel.

E. Stray radiation in the useful beam. For equipment manufactured after September 20, 2006, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that x-ray stray radiation in the useful electron beam, absorbed dose at the surface during x-ray irradiation, and stray neutron radiation in the useful x-ray beam are in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision).

F. Beam monitors. All therapeutic radiation machines subject to this section shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

1. Equipment manufactured after September 20, 2006, shall be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

2. Equipment manufactured on or before September 20, 2006, shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system.

3. The detector and the system into which that detector is incorporated shall meet the following requirements:

a. Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning.

b. Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated.

c. Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation.

d. For equipment manufactured after September 20, 2006, the design of the beam monitoring systems shall ensure that the:

(1) Malfunctioning of one system shall not affect the correct functioning of the other systems; and

(2) Failure of either system shall terminate irradiation or prevent the initiation of radiation.

e. Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after September 20, 2006, each display shall:

(1) Maintain a reading until intentionally reset;

(2) Have only one scale and no electrical or mechanical scale multiplying factors;

(3) Utilize a design such that increasing dose is displayed by increasing numbers; and

(4) In the event of power failure, the beam monitoring information required in subdivision 3 e (3) of this subsection displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20-minute period of time.

G. Beam symmetry.

1. A bent-beam linear accelerator with beam flattening filter subject to this section shall be provided with an auxiliary device to monitor beam symmetry;

2. The device referenced in subdivision 1 of this subsection shall be able to detect field

asymmetry greater than 10%; and

3. The device referenced in subdivision 1 of this subsection shall be configured to terminate irradiation if the specifications in subdivision 2 of this subsection cannot be maintained.

H. Selection and display of dose monitor units.

1. Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel;

2. The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation;

3. After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

4. For equipment manufactured after September 20, 2006, after termination of irradiation, it shall be necessary for the operator to reset the preselected dose monitor units before irradiation can be initiated.

I. Air kerma rate or absorbed dose rate. For equipment manufactured after September 20, 2006, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. (The radiation detectors specified in subsection F of this section may form part of this system.) In addition:

1. The dose monitor unit rate shall be displayed at the treatment control panel;

2. If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided that terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

3. If the equipment can deliver under any fault conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than 10 times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400 rad); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum values specified in subdivisions 2 and 3 of this subsection for the specified operating conditions. Records of these maximum values shall be maintained at the installation for inspection by the agency.

J. Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy.

1. Each primary system shall terminate irradiation when the preselected number of dose

monitor units has been detected by the system;

2. If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15% or 40 dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

3. For equipment manufactured after September 20, 2006, an indicator on the control panel shall show which monitoring system has terminated irradiation.

K. Termination of irradiation. It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

L. Interruption of irradiation. If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.

M. Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

1. A timer shall be provided which has a display at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator;

2. The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems have not previously terminated irradiation.

N. Selection of radiation type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

1. Irradiation shall not be possible until a selection of radiation type (x-rays or electrons) has been made at the treatment control panel;

2. The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

3. An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type that has been selected;

4. An interlock system shall be provided to prevent irradiation with x-rays, except to obtain an image, when electron applicators are fitted;

5. An interlock system shall be provided to prevent irradiation with electrons when

accessories specific for x-ray therapy are fitted; and

6. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

O. Selection of energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

2. The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;

3. Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and

4. For equipment manufactured after September 20, 2006, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1.

P. Selection of stationary beam radiation therapy or moving beam radiation therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

1. Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;

2. The mode of operation shall be displayed at the treatment control panel;

3. An interlock system shall be provided to ensure that the equipment can operate only in the mode that has been selected;

4. An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

5. Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after September 20, 2006:

a. An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of rotation or one centimeter of linear motion differs by more than 20% from the selected value;

b. Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than 5.0% from the dose monitor unit value selected;

c. An interlock shall be provided to prevent motion of more than five degrees or one centimeter beyond the selected limits during moving beam radiation therapy;

d. An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units that are capable of both clockwise and counter-clockwise moving beam radiation therapy;

e. Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement;

6. Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by subsection J of this section; and

7. For equipment manufactured after September 20, 2006, an interlock system shall be provided to terminate irradiation if movement:

a. Occurs during stationary beam radiation therapy; or

b. Does not start or stops during moving beam radiation therapy unless such stoppage is a pre-planned function.

Q. Facility design requirements for therapeutic radiation machines operating above 500 kV. In addition to shielding adequate to meet requirements of 12VAC5-481-3450 , the following design requirements are made:

1. Protective barriers. All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors;

2. Control panel. In addition to other requirements specified in Part XV (12VAC5-481-3380 et seq.) of this chapter, the control panel shall also:

a. Be located outside the treatment room;

b. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

c. Provide an indication of whether radiation is being produced; and

d. Include an access control (locking) device that will prevent unauthorized use of the therapeutic radiation machine;

3. Viewing systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational;

4. Aural communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic

radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible;

5. Room entrances. Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF";

6. Entrance interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel;

7. Beam interceptor interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 12VAC5-481-720 , interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier;

8. Emergency cutoff switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by subsection K of this section. All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch;

9. Safety interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine; and

10. Surveys for residual radiation. Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production.

R. Qualified medical physicist support.

1. The services of a qualified medical physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The qualified medical physicist shall be responsible for:

a. Full calibrations required by subsection T of this section and protection surveys required by 12VAC5-481-3400 A;

b. Supervision and review of dosimetry;

c. Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

d. Quality assurance, including quality assurance check review required by subdivision U 5 of this section;

e. Consultation with the authorized user in treatment planning, as needed; and

f. Performance of calculations or assessments regarding misadministrations.

2. If the qualified medical physicist is not a full-time employee of the registrant, the operating procedures required by subsection S of this section shall also specifically address how the qualified medical physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the qualified medical physicist can be contacted.

S. Operating procedures.

1. No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

2. Therapeutic radiation machines shall not be made available for medical use unless the requirements of 12VAC5-481-3400 A, and subsections T and U of this section have been met;

3. Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

4. When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light field;

5. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and

6. A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

T. Acceptance testing, commissioning, and full calibration measurements.

1. Acceptance testing, commissioning and full calibration of a therapeutic radiation machine subject to this section shall be performed by, or under the direct supervision of, a qualified medical physicist.

2. Acceptance testing and commissioning shall be performed in accordance with the American Association of Physicists in Medicine (AAPM) AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report Number 47," prepared by Radiation Therapy Task Group 45 and the manufacturer's contractual specifications. Acceptance testing and commissioning shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

3. Full calibration shall include measurement of all parameters required by Table II of "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy: AAPM Report No. 46," prepared by Committee Task Group 40 and shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47" prepared by Radiation Therapy Task Group 45. Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies)

shall be completed at intervals not exceeding 12 calendar months, unless a more frequent interval is required in Table II.

4. The qualified medical physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

a. Whenever quality assurance check measurements indicate that the radiation output differs by more than 5.0% from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multienergy or multimode capabilities shall only require measurements for those modes or energies that are not within their acceptable range; and

b. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes or energies, measurements shall be performed on the effected mode or energy that is in most frequent clinical use at the facility. The remaining energies or modes may be validated with quality assurance check procedures against the criteria in subdivision 4 a of this subsection.

5. The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include the date of the calibration; the manufacturer's name, model number, and serial number for the therapeutic radiation machine; the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and the signature of the qualified medical physicist responsible for performing the calibration.

U. Periodic quality assurance checks.

1. Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to this section at intervals not to exceed those specified in "Comprehensive QA for Radiation Oncology: AAPM Report No. 46," prepared by AAPM Radiation Therapy Committee Task Group 40;

2. To satisfy the requirement of subdivision 1 of this subsection, quality assurance checks shall include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in "Comprehensive QA for Radiation Oncology: AAPM Report No. 46" prepared by AAPM Radiation Therapy Committee Task Group 40. Representative sampling shall include all referenced periodic quality assurance checks in an interval not to exceed 12 consecutive calendar months;

3. The registrant shall use a dosimetry system that has been inter-compared within the previous 12 months with the dosimetry system described in 12VAC5-481-3400 C 1 to make the periodic quality assurance checks required in subdivision 2 of this subsection;

4. The registrant shall perform periodic quality assurance checks required by subdivision 1 of this subsection in accordance with procedures established by the qualified medical physicist;

5. The registrant shall review the results of each periodic radiation output check according

to the following procedures:

a. The authorized user and qualified medical physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the qualified medical physicist has determined that all parameters are within their acceptable tolerances;

b. If all quality assurance check parameters appear to be within their acceptable ranges, the quality assurance check shall be reviewed and signed by either the authorized user or qualified medical physicist within three treatment days; and

c. The qualified medical physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 30 days.

6. Therapeutic radiation machines subject to this section shall have applicable safety quality assurance checks listed in "Comprehensive QA for Radiation Oncology: AAPM Report No. 46," prepared by AAPM Radiation Therapy Committee Task Group 40 performed at intervals not to exceed one week;

7. To satisfy the requirement of subdivision 6 of this subsection, safety quality assurance checks shall ensure proper operation of:

a. Electrical interlocks at each external beam radiation therapy room entrance;

b. Proper operation of the "BEAM-ON," interrupt, and termination switches;

c. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

d. Viewing systems;

e. Electrically operated treatment room doors from inside and outside the treatment room;

f. At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.

8. The registrant shall promptly repair any system identified in subdivision 7 of this subsection that is not operating properly; and

9. The registrant shall maintain a record of each quality assurance check required by subdivisions 1 and 7 of this subsection for three years. The record shall include: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name, model number and serial number for the instruments used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

V. Quality assurance checks for intensity modulated radiation therapy (IMRT) shall:

1. Include commissioning and testing of the treatment planning and delivery systems, routine quality assurance of the delivery system, and patient-specific validation of treatment plans;

2. Be performed in accordance with "Guidance document on delivery, treatment planning, and clinical implementation of IMRT: Report of the IMRT subcommittee of the AAPM radiation therapy committee: AAPM Report No. 82"; and

3. Be performed in accordance with the manufacturer's contractual specifications.

12VAC5-481-3440. Calibration of Survey Instruments.

A. The registrant shall ensure that the survey instruments used to show compliance with Part XV (12VAC5-481-3380 et seq.) of this chapter have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

B. To satisfy the requirements of subsection A of this section, the registrant shall:

1. Calibrate all required scale readings up to 10 mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST);

2. Calibrate at least two (2) points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of full-scale; and

C. To satisfy the requirements of subsection B of this section, the registrant shall:

1. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10%; and

2. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20% if a correction factor or graph is conspicuously attached to the instrument.

D. The registrant shall retain a record of each calibration required in subsection A of this section for three years. The record shall include:

1. A description of the calibration procedure; and

2. A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

E. The registrant may obtain the services of individuals licensed by the agency, the NRC, or another agreement state to perform calibrations of survey instruments. Records of calibrations that contain information required by subsection D of this section shall be maintained by the registrant.

12VAC5-481-3450. Shielding and Safety Design Requirements.

A. Each therapeutic radiation machine subject to 12VAC5-481-3420 or 12VAC5-481-3430 shall be provided with such primary or secondary barriers as are necessary to ensure compliance with 12VAC5-481-640 and 12VAC5-481-720 .

B. Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for agency approval prior to actual installation of the therapeutic radiation machine. At a minimum, facility design information shall include:

1. All therapeutic radiation machines.

a. Basic facility information including name, telephone number, and agency registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address, including room number, of the therapeutic radiation machine facility. The plan shall also indicate whether this is a new structure or a modification to an existing structure.

b. The primary areas where all wall, floor, and ceiling areas are struck by the useful beam.

c. The secondary barriers where all wall, floor, and ceiling areas do not have primary barriers.

2. Therapeutic radiation machines less than or equal to 150 kV (photons only). In addition to the requirements listed in subdivision 1 of this subsection, therapeutic radiation machine facilities that produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans that contain, at a minimum, the following additional information:

a. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors;

b. Maximum design workload for the facility including total weekly radiation output, expressed in gray (rad) or air kerma at one meter; total beam-on time per day or per week; average treatment time per patient; and the anticipated number of patients to be treated per day or per week;

c. A facility blueprint or drawing indicating scale (0.25 inch equals 1 foot is typical); direction of north; normal location of the therapeutic radiation machine's radiation port; the port's travel and traverse limits; general direction of the useful beam; locations of any windows and doors; and location of the therapeutic radiation machine control panel. If the control panel is located inside the therapeutic radiation machine treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with 12VAC5-481-640 ;

d. The structural composition and thickness or lead or concrete equivalent of all walls,

doors, partitions, floor, and ceiling of the room concerned;

e. The type of occupancy of all adjacent areas inclusive of space above and below the room concerned. If there is an exterior wall, the distance to the closest areas where it is likely that individuals may be present shall be included; and

f. At least one example calculation that shows the methodology used to determine the amount of shielding required for each physical condition (e.g., primary, secondary, and leakage barriers; restricted and unrestricted areas; and entry doors) and shielding material in the facility:

(1) If commercial software is used to generate shielding requirements, the software used and the version and revision date shall be identified.

(2) If the software used to generate shielding requirements is not in the open literature, quality control sample calculations to verify the result obtained with the software shall be submitted.

3. Therapeutic radiation machines over 150 kV. In addition to the requirements listed in subdivision 1 of this subsection, therapeutic radiation machine facilities that produce photons with a maximum energy in excess of 150 kV or electrons, or both, shall submit shielding plans that contain, at a minimum, the following additional information:

a. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, gray (rad) at the isocenter, and the energy and type of radiation produced (e.g., photon, electron). The target to isocenter distance shall be specified;

b. Maximum design workload for the facility including total weekly radiation output, expressed in gray (rad) at one meter; total beam-on time per day or per week; the average treatment time per patient; and the anticipated number of patients to be treated per day or per week;

c. Facility blueprint or drawing, including both floor plan and elevation views, indicating relative orientation of the therapeutic radiation machine; scale (0.25 inch equals 1 foot is typical); type, thickness, and minimum density of shielding material; direction of north, locations and size of all penetrations through each shielding barrier (ceiling, walls, and floor); and details of the door and maze;

d. The structural composition and thickness or concrete equivalent of walls, doors, partitions, floor, and ceiling of the room concerned;

e. The type of occupancy of all adjacent areas inclusive of space above and below the room concerned. If there is an exterior wall, the distance to the closest areas where it is likely that individuals may be present shall be included;

f. Description of all assumptions that were used in shielding calculations including, but not limited to, design energy (e.g., room may be designed for 6 MV unit although only a 4 MV unit is currently proposed), workload, presence of integral beam-stop in unit,

occupancy and use of adjacent areas, fraction of time that useful beam will intercept each permanent barrier (walls, floor, and ceiling), and "allowed" radiation exposure in both restricted and unrestricted areas; and

g. At least one example calculation that shows the methodology used to determine the amount of shielding required for each physical condition (e.g., primary, secondary, and leakage barriers; restricted and unrestricted areas; small angle scatter; entry doors; and maze), and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, the software used and the version and revision date shall be identified; and

(2) If the software used to generate shielding requirements is not in the open literature, quality control sample calculations to verify the result obtained with the software shall be submitted.

4. Neutron shielding. In addition to the requirements listed in subdivision 3 of this subsection, therapeutic radiation machine facilities that are capable of operating above 10 MV shall submit shielding plans that contain, at a minimum, the following additional information:

a. The structural composition, thickness, minimum density, and location of all neutron shielding material;

b. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluence rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas;

c. At least one example calculation that shows the methodology used to determine the amount of neutron shielding required for each physical condition (e.g., restricted and unrestricted areas, entry doors, and maze), and neutron shielding material utilized in the facility.

(1) If commercial software is used to generate shielding requirements, the software used and the version and revision date shall be identified; and

(2) If the software used to generate shielding requirements is not in the open literature, control sample calculations to verify the result obtained with the software shall be submitted.

d. The methods and instrumentation that will be used to verify the adequacy of all neutron shielding installed in the facility.

12VAC5-481-3451. Quality Assurance for Radiation Therapy Simulation Systems.

Quality assurance for a conventional or virtual simulator shall include acceptance testing and periodic verification of system performance and shall be performed in accordance with (i)

"Comprehensive QA for Radiation Oncology: AAPM Report No. 46, Report of AAPM Radiation Therapy Committee Task Group No.40" for a conventional simulator or (ii) "Quality assurance for computed tomography simulators and the computed tomography-simulation process: AAPM Report No. 83, Report of the AAPM Radiation Therapy Committee Task Group No. 66" for a virtual simulator.

12VAC5-481-3452. Electronic Brachytherapy.

A. Applicability. Electronic brachytherapy devices shall be subject to the requirements of this section and shall be exempt for the requirements of 12VAC5-481-3420 .

1. An electronic brachytherapy device that does not meet the requirements of this section shall not be used for irradiation of patients; and

2. An electronic brachytherapy device shall only be utilized for human use applications specifically approved by the U.S. Food and Drug Administration (FDA) unless participating in a research study approved by the registrant's institutional review board (IRB).

B. Possession of survey instruments. Each facility location authorized to use an electronic brachytherapy device in accordance with this section shall have access to appropriately calibrated portable monitoring equipment. At a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 µSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instruments shall be operable and calibrated in accordance with 12VAC5-481-3440 for the applicable electronic brachytherapy source energy.

C. Facility design requirements for electronic brachytherapy devices. In addition to shielding adequate to meet requirements of 12VAC5-481-3450 , the treatment room shall meet the following design requirements:

1. If applicable, provision shall be made to prevent simultaneous operation of more than one therapeutic radiation machine in a treatment room.

2. Access to the treatment room shall be controlled by a door at each entrance.

3. Each treatment room shall have provisions to permit continuous aural communication and visual observation of the patient from the treatment control panel during irradiation. The electronic brachytherapy device shall not be used for patient irradiation unless the patient can be observed.

4. For electronic brachytherapy devices capable of operating below 50 kV, radiation shielding for the staff in the treatment room shall be available, either as a portable shield or as localized shielded material around the treatment site.

5. For electronic brachytherapy devices capable of operating at greater than 150 kV:

a. The control panel shall be located outside the treatment room; and

b. Electrical interlocks shall be provided for all doors to the treatment room that will:

(a) Prevent the operator from initiating the treatment cycle unless each treatment room

entrance door is closed;

(b) Cause the source to be shielded when an entrance door is opened; and

(c) Prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off control is reset at the console.

D. Electrical safety for electronic brachytherapy devices.

1. The high voltage transformer shall be electrically isolated to prevent electrical and magnetic interference with the surrounding environment and ancillary equipment.

2. The high voltage transformer shall be isolated from personnel (e.g., an operator) and the environment by a protective housing that can only be accessed through a cover requiring a tool for access or with electrical interlocks to prevent operation while open.

3. The high voltage transformer shall have appropriate safety labels warning personnel of potential electrical shock or heat related injuries.

4. Equipment manufactured after March 2009 shall be in compliance with the most current revision of the following International Electrotechnical Commission (IEC) Documents:

a. IEC 60601-1:1998+A1+A2:1995;

b. IEC 60601-1-2:2001;

c. IEC 60601-2-8:1999; and

d. IEC 60601-2-17:2004.

E. Control panel functions. The control panel, in addition to the displays required by other provisions in this section, shall:

1. Provide an indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;

2. Provide an indication of whether x-rays are being produced;

3. Provide a means for indicating electronic brachytherapy source potential and current;

4. Provide the means for terminating an exposure at any time; and

5. Include an access control (locking) device that will prevent unauthorized use of the electronic brachytherapy device.

F. Timer. A suitable irradiation control device (timer) shall be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor.

1. A timer shall be provided at the treatment control panel. The timer shall indicate planned setting and the time elapsed or remaining;

2. The timer shall not permit an exposure if set at zero;

3. The timer shall be a cumulative device that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

4. The timer shall terminate irradiation when a preselected time has elapsed if any dose monitoring system has not previously terminated irradiation;

5. The timer shall permit setting of exposure times as short as 0.1 second; and

6. The timer shall be accurate to within 1.0% of the selected value or 0.1 second, whichever is greater.

G. Qualified medical physicist support.

1. The services of a qualified medical physicist shall be required in facilities having electronic brachytherapy devices. The qualified medical physicist shall be responsible for:

a. Evaluation of the output from the electronic brachytherapy source;

b. Generation of the necessary dosimetric information;

c. Supervision and review of treatment calculations prior to initial treatment of any treatment site;

d. Establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required in subsection K of this section;

e. Consultation with the authorized user in treatment planning, as needed; and

f. Performing calculations or assessments regarding patient treatments that may constitute a misadministration.

2. If the qualified medical physicist is not a full-time employee of the registrant, the operating procedures required by subsection H of this section shall also specifically address how the qualified medical physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the qualified medical physicist can be contacted.

H. Operating procedures.

1. Only individuals approved by the authorized user, radiation safety officer, or qualified medical physicist shall be present in the treatment room during treatment;

2. Electronic brachytherapy devices shall not be made available for medical use unless the requirements of 12VAC5-481-3400 A and subsections I and J of this section have been met;

3. The electronic brachytherapy device shall be inoperable, either by hardware or password, when unattended by qualified staff or service personnel;

4. During operation, the electronic brachytherapy device operator shall monitor the position of all persons in the treatment room and all persons entering the treatment room

to prevent entering persons from unshielded exposure from the treatment beam;

5. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used;

6. Written procedures shall be developed, implemented, and maintained for responding to an abnormal situation. These procedures shall include:

a. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions; and

b. The names and telephone numbers of the authorized users, the qualified medical physicist, and the radiation safety officer to be contacted if the device or console operates abnormally;

7. A copy of the current operating and emergency procedures shall be physically located at the electronic brachytherapy device control console. If the control console is integral to the electronic brachytherapy device, the required procedures shall be kept where the operator is located during electronic brachytherapy device operation;

8. Instructions shall be posted at the electronic brachytherapy device control console to inform the operator of the names and telephone numbers of the authorized users, the qualified medical physicist, and the radiation safety officer to be contacted if the device or console operates abnormally; and

9. The radiation safety officer, or his designee, and an authorized user shall be notified as soon as possible if the patient has a medical emergency, suffers injury, or dies. The radiation safety officer or the qualified medical physicist shall inform the manufacturer of the event.

I. Safety precautions for electronic brachytherapy devices.

1. A qualified medical physicist shall determine which persons in the treatment room require monitoring when the beam is energized;

2. An authorized user and a qualified medical physicist shall be physically present during the initiation of all patient treatments involving the electronic brachytherapy device;

3. A qualified medical physicist and either an authorized user or a nonauthorized user (physician or electronic brachytherapy device operator) under the supervision of an authorized user, who has been trained in the operation and emergency response for the electronic brachytherapy device, shall be physically present during continuation of all patient treatments involving the electronic brachytherapy device;

4. When shielding is required by subdivision C 4 of this section, the electronic brachytherapy device operator shall use a survey meter to verify proper placement of the shielding immediately upon initiation of treatment. Alternatively, a qualified medical physicist shall designate shield locations sufficient to meet the requirements of 12VAC5-481-640 for any individual, other than the patient, in the treatment room; and

5. All personnel in the treatment room shall remain behind shielding during treatment. A qualified medical physicist shall approve any deviation from this requirement and shall designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.

J. Electronic brachytherapy source calibration measurements.

1. Calibration of the electronic brachytherapy source output for an electronic brachytherapy device subject to this section shall be performed by or under the direct supervision of a qualified medical physicist;

2. Calibration of the electronic brachytherapy source output shall be made for each electronic brachytherapy source after any repair affecting the x-ray beam generation, or when indicated by the electronic brachytherapy source quality assurance checks;

3. Calibration of the electronic brachytherapy source output shall utilize a dosimetry system described in 12VAC5-481-3400 C;

4. Calibration of the electronic brachytherapy source output shall include, as applicable, determination of:

a. The output within 2.0% of the expected value, if applicable, or determination of the output if there is no expected value;

b. Timer accuracy and linearity over the typical range of use;

c. Proper operation of back-up exposure control devices;

d. Evaluation that the relative dose distribution about the source is within 5.0% of that expected; and

e. Source positioning accuracy to within one millimeter within the applicator;

5. Calibration of the x-ray source output required by subdivisions 1 through 4 of this subsection shall be in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy, when available. In the absence of a calibration protocol published by a national professional association, the manufacturer's calibration protocol shall be followed; and

6. The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include the date of the calibration; the manufacturer's name, model number, and serial number for the electronic brachytherapy device and a unique identifier for its electronic brachytherapy source; the model numbers and serial numbers of the instrument used to calibrate the electronic brachytherapy device; and the name and signature of the qualified medical physicist responsible for performing the calibration.

K. Periodic and day-of-use quality assurance checks for electronic brachytherapy devices.

1. Quality assurance checks shall be performed on each electronic brachytherapy device:

a. At the beginning of each day of use;

b. Each time the device is moved to a new room or each day of use at each operating location for a self-contained electronic brachytherapy unit transported in a van or trailer; and

c. After each x-ray tube installation.

2. The registrant shall perform periodic quality assurance checks required by subdivision 1 of this subsection in accordance with procedures established by the qualified medical physicist.

3. To satisfy the requirements of subdivision 1 of this subsection, radiation output quality assurance checks shall include at a minimum:

a. Verification that output of the electronic brachytherapy source falls within 3.0% of expected values, as appropriate for the device, as determined by:

(1) Output as a function of time, or

(2) Output as a function of setting on a monitor chamber.

b. Verification of the consistency of the dose distribution to within 3.0% of that found during calibration required by subsection J of this section; and

c. Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within one millimeter.

4. The registrant shall use a dosimetry system that has been intercompared within the previous 12 months with the dosimetry system described in 12VAC5-481-3400 C 1 to make the quality assurance checks required in subdivision 3 of this subsection.

5. The registrant shall review the results of each radiation output quality assurance check according to the following procedures:

a. An authorized user and qualified medical physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The electronic brachytherapy device shall not be made available for subsequent medical use until the qualified medical physicist has determined that all parameters are within the acceptable tolerances;

b. If all radiation output quality assurance check parameters appear to be within the acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or qualified medical physicist within two days; and

c. The qualified medical physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 30 days.

6. To satisfy the requirements of subdivision 1 of this subsection, safety device quality assurance checks shall, at a minimum, assure:

a. Proper operation of radiation exposure indicator lights on the electronic

brachytherapy device and on the control console;

b. Proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable;

c. Proper operation of radiation monitors, if applicable;

d. The integrity of all cables, catheters, or parts of the device that carry high voltages; and

e. Connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.

7. If the results of the safety device quality assurance checks required in subdivision 6 of this subsection indicate the malfunction of any system, a registrant shall secure the control console in the "OFF" position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning system.

8. The registrant shall maintain a record of each quality assurance check required by subdivisions 3 and 7 of this subsection in an auditable form for three years.

a. The record shall include the date of the quality assurance check; the manufacturer's name, model number, and serial number for the electronic brachytherapy device; the name and signature of the individual who performed the periodic quality assurance check; and the name and signature of the qualified medical physicist who reviewed the quality assurance check; and

b. For radiation output quality assurance checks required by subdivision 3 of this subsection, the record shall also include the unique identifier for the electronic brachytherapy source and the manufacturer's name, model number, and serial number for the instrument used to measure the radiation output of the electronic brachytherapy device.

L. Therapy-related computer systems. The registrant shall perform acceptance testing on the treatment planning system of electronic brachytherapy-related computer systems in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy, when available. In the absence of an acceptance testing protocol published by a national professional association, the manufacturer's acceptance testing protocol shall be followed.

1. Acceptance testing shall be performed by or under the direct supervision of a qualified medical physicist. At a minimum, the acceptance testing shall include, as applicable, verification of:

a. The source-specific input parameters required by the dose calculation algorithm;

b. The accuracy of dose, dwell time, and treatment time calculations at representative points;

c. The accuracy of isodose plots and graphic displays;

d. The accuracy of the software used to determine radiation source positions from radiographic images; and

e. If the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

2. The position indicators in the applicator shall be compared to the actual position of the source or planned dwell positions, as appropriate, at the time of commissioning.

3. Prior to each patient treatment regimen, the parameters for the treatment shall be evaluated and approved by the authorized user and the qualified medical physicist for correctness through means independent of that used for the determination of the parameters.

M. Training.

1. A registrant shall provide instruction, initially and at least annually, to all individuals who operate the electronic brachytherapy device, as appropriate to the individual's assigned duties, in the operating procedures identified in subsection H of this section. If the interval between patients exceeds one year, retraining of the individuals shall be provided.

2. In addition to the requirements of 12VAC5-481-3390 C for therapeutic radiation machine authorized users and 12VAC5-481-3390 D for qualified medical physicists, the therapeutic radiation machine authorized users and qualified medical physicists shall also receive device-specific instruction initially from the manufacturer and annually from either the manufacturer or other qualified trainer. The training shall be of a duration recommended by a recognized national professional association with expertise in electronic brachytherapy, when available. In the absence of any training protocol recommended by a national professional association, the manufacturer's training protocol shall be followed. The training shall include, but not be limited to:

a. Device-specific radiation safety requirements;

b. Device operation;

c. Clinical use for the types of use approved by the U.S. Food and Drug Administration;

d. Emergency procedures, including an emergency drill; and

e. The registrant's quality assurance program.

3. A registrant shall retain a record of individuals receiving instruction required by subdivisions 1 and 2 of this subsection for three years. The record shall include a list of the topics covered, the date of the instruction, the names of the attendees, and the names of the individuals who provided the instruction.

N. Mobile electronic brachytherapy service. A registrant providing mobile electronic brachytherapy service shall, at a minimum:

1. Check all survey instruments before medical use at each address of use or on each day of use, whichever is more restrictive.

2. Account for the electronic brachytherapy source in the electronic brachytherapy device before departure from the client's address.

3. Perform at each location on each day of use all of the required quality assurance checks specified in subsection K of this section to assure proper operation of the device.

12VAC5-481-3453. Other Use of Electronically Produced Radiation to Deliver Therapeutic Radiation Dosage.

A person shall not utilize any device that is designed to electronically generate a source of ionizing radiation to deliver therapeutic radiation dosage and that is not appropriately regulated under any existing category of therapeutic radiation machine until:

1. The applicant or registrant has, at a minimum, provided the agency with:

   a. A detailed description of the device and its intended application;

   b. Facility design requirements, including shielding and access control;

   c. Documentation of appropriate training for authorized user physicians and qualified medical physicists;

   d. Methodology for measurement of dosages to be administered to patients or human research subjects;

   e. Documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for radiation safety;

   f. Radiation safety precautions and instructions; and

   g. Other information requested by the agency in its review of the application; and

2. The applicant or registrant has received written approval from the agency to utilize the device in accordance with the regulations and specific conditions the agency considers necessary for the medical use of the device.

12VAC5-481-3460. Purpose.

Part XVI. Regulation and Licensing of Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM)

This part establishes radiation protection standards for the possession, use, transfer, and disposal of Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM).

12VAC5-481-3470. Scope.

A. These regulations apply to any person who receives, owns, possesses, uses, processes, transfers, distributes, or disposes of TENORM.

B. The regulations in this part address the introduction of TENORM into products in which neither the TENORM, nor the radiation emitted from the TENORM, is considered to be beneficial to the products.

C. The manufacture and distribution of products containing TENORM, in which the TENORM and/or its emitted radiation is considered to be a beneficial attribute, are licensed under the provisions of Part III (12VAC5-481-380 et seq.) of this chapter.

D. This part does not apply to radionuclides for which NRC retains exclusive jurisdiction.

12VAC5-481-3480. Exemptions.

A. Persons who receive, own, possess, use, process, transfer, distribute, or dispose of TENORM are exempt from the requirements of this part (12VAC5-481-3460 et seq.) of this chapter with respect to any combination of radium-226 and radium-228 if the materials contain, or are contaminated at, concentrations less than 185 Bq/kg (5 pCi/gm) excluding natural background. This does not apply to consumer or retail products that are discussed in 12VAC5-481-3560 C and 12VAC5-481-3570 . Using purposeful dilution to render TENORM waste exempt shall not be allowed without prior agency approval.

B. Persons who receive products or materials containing TENORM distributed in accordance with a specific license issued by the agency pursuant to 12VAC5-481-3540 1, or to an equivalent license issued by another licensing state, are exempt from these regulations with regard to those products or materials.

C. The distribution, including custom blending, possession, and use of fertilizers containing TENORM, is exempt from the requirements of this part.

D. TENORM waste regulated by CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) or RCRA (Resources Conservation and Recovery Act) are exempt from this part.

E. The transportation and storage incident to transportation are governed by other parts of these regulations.

12VAC5-481-3490. Standards for Radiation Protection for Tenorm.

A. No person licensed under 12VAC5 481-3530 or 12VAC5-481-3540 shall conduct operations, use, or transfer TENORM in a manner such that a member of the public will receive an annual total effective dose equivalent in excess of 1mSv (100 mrem) per year from all licensed sources including TENORM.

B. Persons subject to a license under this part shall comply with radiation protection standards set out in Part IV (12VAC5-481-600 et seq.) of this chapter.

C. Doses from indoor radon and its progeny shall not be included in total effective dose equivalent calculations.

D. No person shall release TENORM for unrestricted use in such a manner that the reasonably maximally exposed individual will receive an annual total effective dose equivalent from the

released TENORM in excess of 1mSv (100 mrem) per year excluding natural background.

12VAC5-481-3500. Protection of Workers During Operations.

Each person subject to a specific license under Part XVI of this chapter shall conduct operations in compliance with the standards for radiation protection set out in other parts of these regulations.

12VAC5-481-3510. Release for Unrestricted Use.

Each person subject to a license under this part shall:

1. Not transfer or release for unrestricted use facilities or equipment contaminated with TENORM in excess of levels in Table 6.

Table 6.
Acceptable Surface Contamination Levels[1] for TENORM

	AVERAGE[2,3,6]	MAXIMUM[2,4,6]	REMOVABLE[2,3,5,6]
Alpha	5,000 dpm/100 cm^2	15,000 dpm/100 cm^2	1,000 dpm/100 cm^2
Beta-gamma	5,000 dpm/100 cm^2	15,000 dpm/100 cm^2	1,000 dpm/100 cm^2

[1]Where surface contamination by both alpha andbeta-gamma emitting nuclides exists, the limits established for alpha andbeta-gamma emitting nuclides should apply independently.

[2]As used in this table, dpm (disintegrations perminute) means the rate of emission by radioactive material as determined bycorrecting the counts per minute observed by an appropriate detector forbackground, efficiency, and geometric factors associated with the instrumentation.

[3]Measurements of average contamination levelshould not be averaged over more than one square meter. For objects of lesssurface area, the average should be derived for each object.

[4]The maximum contamination level applies to anarea of not more than 100 cm^2.

[5]The amount of removable radioactive material per100 cm^2 of surface area should be determined by wiping that areawith dry filter or soft absorbent paper, applying moderate pressure, andassessing the amount of radioactive material on the wipe with an appropriateinstrument of known efficiency. When removable contamination on objects ofsurface area A (where A is less than 100 sq. cm) is determined, the entiresurface should be wiped and the contamination level multiplied by 100/A toconvert a "per 100 sq. cm" basis.

[6]The average and minimum radiation levelsassociated with surface contamination resulting from beta-gamma emittersshould not exceed 0.2 mrad/hr (2µGy/hr) at 1 cm, respectively, measuredthrough not more than 7 milligrams per square centimeter of total absorber.

2. Not transfer or release for unrestricted use equipment contaminated with TENORM in excess of a surface gamma radiation level of 200 µrem/hr at 1 cm excluding natural

background; and

3. Not transfer land for unrestricted use where the concentration of radium-226 or radium-228 in soil averaged over any 100 square meters exceeds the background level by more than 185 Bq/kg (5 pCi/gm), averaged over any 15 cm layer of soil below the surface, unless compliance with 12VAC5-481-3490 B through D can be demonstrated.

12VAC5-481-3520. Disposal and Transfer of Waste for Disposal.

A. Each person subject to a license under this part shall manage and dispose of wastes containing TENORM:

1. By transfer of the wastes for disposal to a facility licensed under requirements for uranium or thorium byproduct materials in either 40 CFR Part 192 or 10 CFR Part 40 Appendix R;

2. By transfer of the wastes for disposal to a disposal facility licensed by the NRC, or another agreement state; or

3. In accordance with alternate methods authorized by the agency upon application or upon the agency's initiative, consistent with 12VAC5-481-3490 and where applicable the Clean Water Act, Safe Drinking Water Act and other requirements of the United States Environmental Protection Agency for disposal of such wastes.

B. Equipment contaminated with TENORM in excess of levels specified in Table 6 of this part, which is to be disposed of as waste, shall be disposed of:

1. So as to prevent any reintroduction into commerce or unrestricted use; and

2. Within disposal areas specifically designed to meet the criteria of subsection A of this section.

C. Transfers of waste containing TENORM for disposal shall be made only to a person specifically authorized by the NRC, or another agreement state, to receive such waste.

D. Records of disposal, including manifests, shall be maintained pursuant to the provisions of Part IV (12VAC5-481-600 et seq.) of this chapter.

12VAC5-481-3530. General License.

A. Subject to the requirements of 12VAC5-481-3490 through 12VAC5-481-3520 and 12VAC5-481-3540 , a general license is hereby issued to possess, own, use, transfer, distribute or dispose of TENORM without regard to quantity.

B. This general license does not authorize the manufacturing of products containing TENORM in concentrations greater than those specified in 12VAC5-481-3480 A nor the receipt and disposal of wastes from other persons.

C. The decontamination of equipment, facilities, and land shall be performed only by persons specifically licensed by the agency, NRC or another agreement state to conduct such work. However, employees or contractors under control and supervision of a general licensee can

perform routine maintenance on equipment, facilities, and land owned or controlled by the general licensee. Maintenance that provides a different pathway for exposure than is found in daily operations and that increases the potential for additional exposure is not considered routine.

D. Any person subject to the general license issued by this section shall notify the agency. Such notification shall include:

1. Name and address of the licensee;

2. Location and description of the facility or operation; and

3. Description of the TENORM including estimates of the amount and extent of TENORM.

E. Transfer of material or real property.

1. The transfer of TENORM not exempt from these regulations from one general licensee to another general licensee is authorized if:

a. The equipment and facilities contaminated with TENORM are to be used by the recipient for the same purpose; or

b. The transfer of control or ownership of land contaminated with TENORM includes an annotation of the deed records, or notice to owners of surface and mineral rights, to indicate the presence of TENORM.

2. Transfers not made in accordance with subdivision 1 of this subsection require prior approval by the agency.

3. Transfers made under subdivision 1 of this subsection do not relieve the general licensee who makes the transfer from the responsibilities of assessing the extent of TENORM contamination or material present, informing the general licensee receiving the TENORM of these assessments, and maintaining records required by this chapter.

4. A general licensee intending to transfer material or real property for unrestricted use shall document compliance with the requirements of 12VAC5-481-3510 .

F. Distribution of TENORM products between general licensees. The distribution of TENORM products not exempt from these regulations from one general licensee to another general licensee is authorized provided the product is accompanied by labels or manifests which identify the type and amount of TENORM.

G. The agency may, by written notice, require any person authorized by a general license to apply for and obtain a specific license. The notice shall state the reason or reasons for requiring a specific license.

12VAC5-481-3540. Specific Licenses.

Unless otherwise exempt, a specific license is required to:

1. Manufacture and distribute any material or product containing TENORM unless

authorized by 12VAC5-481-3530 F, exempted under the provisions of 12VAC5-481-3480 , or licensed under the provisions of Part III (12VAC5-481-380 et seq.) of this chapter;

2. Except as provided in 12VAC5-481-3530 C, decontaminate equipment or land not otherwise exempted under the provisions of 12VAC5-481-3480 or facilities contaminated with TENORM in excess of the levels set forth in 12VAC5-481-3510 , as applicable; for purposes of this subsection, the term "decontaminate" shall not include maintenance that incidentally results in removal of contamination;

3. Receive TENORM from other persons for disposal.

12VAC5-481-3550. Filing Application for Specific Licenses.

A. Applications for specific licenses shall be filed in a manner and on a form prescribed by the agency.

B. The agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

C. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on the licensee's behalf.

D. An application for a license may include a request for a license authorizing one or more activities.

E. Each application for a specific license shall be accompanied by a fee of $50.

F. In an application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the agency provided such references are clear and specific.

G. Applications and documents submitted to the agency may be made available for public inspection.

12VAC5-481-3560. Requirements for the Issuance of Specific Licenses.

A. A license application will be approved if the agency determines that:

1. The applicant is qualified by reason of training and experience to use the TENORM in question for the purpose requested in accordance with these rules in such a manner as to protect the public health and safety or property;

2. The applicant's proposed equipment, facilities, and procedures are adequate to protect the public health and safety or property;

3. The issuance of the license will not be inimical to the health and safety of the public;

4. The applicant satisfied all applicable special requirements in this part;

5. The applicant has met the financial surety requirements of 12VAC5-481-450 C; and

6. The applicant has adequately addressed the following items in the application:

a. Procedures and equipment for monitoring and protecting workers;

b. An evaluation of the radiation levels and concentrations of contamination expected during normal operations;

c. Operating and emergency procedures, including procedures for waste reduction and quality assurance of items released for unrestricted use; and

d. A method for managing the radioactive material removed from contaminated equipment and facilities.

B. An application for a specific license to decontaminate equipment, land, or facilities contaminated with TENORM in excess of the levels set forth in 12VAC5-481-3480 A, 12VAC5-481-3510 2, or Table 6, as applicable, and to dispose of the resulting waste will be approved if:

1. The applicant satisfies the general requirements specified in subsection A of this section; and

2. The applicant has adequately addressed the following items in the application:

a. Procedures and equipment for monitoring and protection of workers;

b. An evaluation of the radiation levels and concentrations of contamination expected during normal operations;

c. Operating and emergency procedures, including procedures for waste reduction and quality assurance of items released for unrestricted use; and

d. Method of disposing of the TENORM removed from contaminated equipment, facilities, and/or land.

C. An application for a specific license to transfer materials or manufacture or distribute products containing TENORM to persons exempted from these regulations pursuant to 12VAC5-481-3530 B will be approved if:

1. The applicant satisfies the general requirements specified in subsection A of this section;

2. The TENORM is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being; and

3. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the TENORM material or product to demonstrate that the material or product will meet the safety criteria set forth in 12VAC5-481-3570 . The information shall include:

a. A description of the material or product and its intended use or uses;

b. The type, quantity, and concentration of TENORM in each material or product;

c. The chemical and physical form of the TENORM in the material or product, and changes in chemical and physical form that may occur during the useful life of the material or product;

d. An analysis of the solubility in water and body fluids of the TENORM in the material or product;

e. The details of manufacture and design of the material or product relating to containment and shielding of the TENORM and other safety features under normal and severe conditions of handling, storage, use, reuse, and disposal of the material or product;

f. The degree of access of human beings to the material or product during normal handling, use, and disposal;

g. The total quantity of TENORM expected to be distributed annually in the material or product;

h. The expected useful life of the material or product;

i. The proposed method of labeling or marking each unit of the material or product with identification of the manufacturer or initial transferor of the product and the radionuclides and quantity of TENORM in the material or product;

j. The procedures for prototype testing of the material or product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, reuse, and disposal;

k. The results of the prototype testing of the material or product, including any change in the form of the TENORM contained in it, the extent to which the TENORM may be released to the environment, any change in radiation levels, and any other changes in safety features;

l. The estimated external radiation doses and dose commitments relevant to the safety criteria in 12VAC5-481-3570 and the basis for such estimates;

m. A determination that the probabilities with respect to doses referred to in 12VAC5-481-3570 meet the safety criteria;

n. The quality control procedures to be followed in the production of production lots of the material or product, and the quality control standards the material or product will be required to meet; and

o. Any additional information, including experimental studies and tests, required by the agency to facilitate a determination of the radiation safety of the material or product.

D. Notwithstanding the provisions of subdivision 2 of 12VAC5-481-3570 , the agency may deny an application for a specific license if the end uses of the product are frivolous or cannot be reasonably foreseen.

12VAC5-481-3570. Safety Criteria for Products.

An applicant for a license under 12VAC5-481-3560 C shall demonstrate that the product is designed and will be manufactured so that:

1. In normal use and disposal of a single exempt item, and in normal handling and storage of the quantities of exempt items likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the TEDE in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the doses in Column I of 12VAC5-481-3580 .

2. In use and disposal of a single exempt item and in handling and storage of the quantities of exempt items likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low (not more than one failure per year for each 10,000 exempt units distributed) that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column II of the table in 12VAC5-481-3580 and the probability is negligible (not more than one such failure per year for each one millions exempt units distributed) that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the table in 12VAC5-481-3580 . It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates that are to be made. The above values may be used a guidelines in estimating compliance with the criteria.

3. It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

12VAC5-481-3580. Table of Organ Doses.

Part of Body	Column I (rem)	Column II (rem)	Column III (rem)	Column IV (rem)
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	0.001	0.01	0.5	15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	0.015	0.15	7.5	200

Other organs	0.003	0.03	1.5	50

12VAC5-481-3590. Issuance of Specific Licenses.

A. Upon a determination that an application meets the requirements of these regulations, the agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

B. The agency may incorporate in any license at the time of issuance, or thereafter by amendment, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of TENORM subject to this part as it deems appropriate or necessary in order to:

1. Protect public health and safety or property;

2. Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

3. Prevent loss, theft, or loss of control of TENORM subject to this part.

12VAC5-481-3600. Conditions of Specific Licenses Issued under 12VAC5-481-3560.

A. General terms and conditions.

1. Each license issued pursuant to this part shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the agency.

2. No license issued or granted under this part and no right to possess or utilize TENORM granted by any license issued pursuant to this part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the agency shall, after securing full information, find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing.

3. Each person licensed by the agency pursuant to this part shall confine use and possession of the TENORM licensed to the locations and purposes authorized in the license.

4. Each person licensed by the agency pursuant to this part is subject to the general license provisions of 12VAC5-481-3500 , 12VAC5-481-3510 , and 12VAC5-481-3520 .

5. Each licensee shall:

a. Notify the agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapters of Title II (Bankruptcy) of the United States Code (11 USC) by or against a licensee, an entity (as that term is defined in 11 USC § 101 (15)) controlling a licensee or listing the license or licensee as property of the estate; or an affiliate (as that term is defined in 11 USC § 101 (2)) of the licensee.

b. Indicate in their bankruptcy notification the bankruptcy court in which the petition for bankruptcy was filed; and the date of the filing of the petition.

B. Quality control, labeling, and reports of transfer. Each person licensed under 12VAC5-481-3560 C shall:

1. Carry out adequate control procedures in the manufacture of the product to assure that each production lot meets the quality control standards approved by the agency;

2. Label or mark each unit so that the manufacturer, processor, producer, or initial transferor of the material or product and the TENORM in the product can be identified; and

3. Maintain records identifying, by name and address, each person to whom TENORM is transferred for use under 12VAC5-481-3480 B or the equivalent regulations of another licensing state, and stating the kinds, quantities, and uses of TENORM transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the agency. Each report shall cover the year ending December 31, and shall be filed within 90 days thereafter. If no transfers of TENORM have been made pursuant to 12VAC5-481-3560 C during the reporting period, the report shall so indicate.

12VAC5-481-3610. Expiration and Termination of Specific Licenses.

A. Except as provided in subdivision D 6 of this section and 12VAC5-481-3620 B, each specific license shall expire at the end of the specified day in the month and year stated therein.

B. Each licensee shall notify the agency in writing and request termination of the license when the licensee decides to terminate all activities involving TENORM authorized under the license. This notification and request for termination of the license must include the reports and information specified in subdivision D 4 of this section. The licensee is subject to the provisions of subsections D and E of this section, as applicable.

C. No less than 30 days before the expiration date specified in a specific license, the licensee shall either:

1. Submit an application for license renewal under 12VAC5-481-3620; or

2. Notify the agency in writing, under subsection B of this section, if the licensee decides to discontinue all activities involving TENORM.

D. If a licensee does not submit an application for license renewal under 12VAC5-481-3620 , the licensee shall, on or before the expiration date specified in the license:

1. Terminate use of TENORM;

2. Remove TENORM contamination consistent with the requirements of 12VAC5-481-3510 .

3. Properly dispose of TENORM; and

4. Submit a report of disposal of TENORM and radiation surveys to confirm the absence of TENORM or to establish the levels of residual TENORM contamination. The licensee shall, as appropriate:

a. Report levels of radiation in units of microroentgens per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces and report levels of radioactivity in units of disintegrations per minute (or microcuries) per 100 square centimeters removable and fixed on surfaces, microcuries or Becquerel per milliliter in water, and picocuries or becquerels per gram in contaminated solids such as soils or concrete; and

b. Specify the instruments used and certify that each instrument is properly calibrated and tested.

5. If levels of residual activity are less than those established in 12VAC5-481-3510 , the licensee shall so certify. If the agency determines that this certification and the information submitted under subdivision 4 of this subsection is adequate and surveys confirm the findings, the agency will notify the licensee in writing that the license is terminated.

6. If levels of residual TENORM are not in conformance with criteria established in 12VAC5-481-3510 , the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual TENORM until the agency notifies the licensee in writing that the license is terminated. During this time, the licensee is subject to the provisions of subsection E of this section. In addition to the information submitted under subdivision 4 of this subsection, the licensee shall submit a plan, if appropriate, for decontaminating the location(s) and disposing of this subsection of the residual TENORM.

E. Each licensee who possesses residual TENORM under subdivision D 6 of this section, following the expiration date specified in the license, shall:

1. Be limited to actions involving TENORM related to preparing the locations for release for unrestricted use; and

2. Continue to control entry to restricted areas until the locations are suitable for release for unrestricted use and the agency notifies the licensee in writing that the license is terminated.

12VAC5-481-3620. Renewal of Specific Licenses.

A. Applications for renewal of specific licenses shall be filed in accordance with 12VAC5-481-3550 .

B. In any case in which a licensee, not less than 30 days prior to expiration of an existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the agency.

12VAC5-481-3630. Amendment of Specific Licenses at Request of Licensee.

Applications for amendment of a license shall be filed in accordance with 12VAC5-481-3550 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

12VAC5-481-3640. Agency Action on Applications to Renew and Amend Specific Licenses.

In considering an application by a licensee to renew or amend the license, the agency will apply the criteria set forth in 12VAC5-481-3560 .

12VAC5-481-3650. Modification and Revocation of Specific Licenses.

A. The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act, or by reason of rules, regulations, and orders issued by the agency.

B. Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule, regulation, or order of the agency.

C. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, the agency shall not modify, suspend or revoke a license prior to the institution of proceedings unless facts or conduct that may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

12VAC5-481-3660. Reciprocal Recognition of Specific Licenses.

Subject to these regulations, any person who holds a specific license from an agreement state or a licensing state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in any calendar year provided that:

1. The licensing document does not limit the activity authorized by such document to specified installations or locations;

2. The out-of-state licensee notifies the agency in writing at least three days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following

the receipt of the initial notification from a person engaging in activities under the general license provided in subdivision 1 of this section;

3. The out-of-state licensee complies with all applicable regulations of the agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the agency;

4. The out-of-state licensee supplies such other information as the agency may request; and

5. The out-of-state licensee shall not transfer or dispose of TENORM possessed or used under the general license provided in subsection A of this section, except by transfer to a person:

a. Specifically licensed by the agency or by another licensing state to receive such TENORM; or

b. Exempt from the requirements for a license for such TENORM under 12VAC5-481-3480 .

12VAC5-481-3670. (Repealed.)

12VAC5-481-3680. Assigned Protection Factors for Respirators[A].

Part XVII. Schedules

	Operating mode	Assigned Protection Factors
I. Air Purifying Respirators (Particulate[b] only)[c]:		
Filtering facepiece disposable[d]	Negative Pressure	(d)
Facepiece, half[e]	Negative Pressure	10
Facepiece, full	Negative Pressure	100
Facepiece, half	Powered air-purifying respirators	50
Facepiece, full	Powered air-purifying respirators	1000
Helmet/hood	Powered air-purifying respirators	1000
Facepiece, loose-fitting	Powered air-purifying respirators	25
II. Atmosphere-supplying respirators (particulate, gases and vapors[f]):		

1. Air-line respirator:		
Facepiece, half	Demand	10
Facepiece, half	Continuous Flow	50
Facepiece, half	Pressure Demand	50
Facepiece, full	Demand	100
Facepiece, full	Continuous Flow	1000
Facepiece, full	Pressure Demand	1000
Helmet/hood	Continuous Flow	1000
Facepiece, loose-fitting	Continuous Flow	25
Suit	Continuous Flow	[g]
2. Self-contained breathing Apparatus (SCBA):		
Facepiece, full	Demand	[h]100
Facepiece, full	Pressure Demand	[i]10,000
Facepiece, full	Demand, Recirculating	[h]100
Facepiece, full	Positive Pressure Recirculating	[i]10,000
III. Combination Respirators:		
Any combination of air-purifying and atmosphere-supplying respirators	Assigned protection factor for type and mode of operation as listed above.	

[a]These assigned protection factors apply only in a respiratory protection program that meets the requirements of this section. They are applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards. Selection and use of respirators for such circumstances shall also comply with Department of Labor regulations.

Radioactive contaminants for which the concentration values in Table 1, Column 3 of Appendix B to 10 CFR Part 20 are based on internal dose due to inhalation may, in addition, present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

[b]Air purifying respirators with APF <100shall be equipped with particulate filters that are at least 95% efficient. Air purifying respirators with APF = 100 shall be equipped with particulate filters that are at least 99% efficient. Air purifying respirators with APFs >100 shall be equipped with particulate filters that are at least 99.97% efficient.

[c]The licensee may apply to VDH for the use of an APF greater than 1 for absorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine).

[d]Licensees may permit individuals to use this type of respirator who have not been medically screened or fit tested on the device provided that no credit be taken for their use in estimating intake or dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use user seal check on this type of device. All other respiratory protection program requirements listed in 12VAC5-481-820 apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to 10 may be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.

[e]Under-chin type only. No distinction is made in this section between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (e.g., disposable or reusable disposable). Both types are acceptable so long as the seal area of the latter contains some substantial type of seal-enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least 95 percent efficient and all other requirements of this section are met.

[f]The assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.

[g]No NIOSH approval schedule is currently available for atmosphere supplying suits. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements, with the exception of fit testing, are met (i.e., 12VAC5-481-820).

[h]The licensee should implement institutional controls to assure that these devices are not used in areas immediately dangerous to life or health (IDLH).

[i]This type of respirator may be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure such as skin absorption shall be taken into account in these circumstances. This device may not be used by any individual who experiences perceptible outward leakage of breathing gas while wearing the device.

12VAC5-481-3690. (Repealed.)

12VAC5-481-3700. Quantities of Licensed Materials Requiring Labeling.

NOTE: For purposes of 10 CFR 20.1902(e), 10 CFR 20.1905(a), and 10 CFR 20.2201(a) where there is involved a combination of radionuclides in known amounts, the limit for the combination should be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1" (i.e., "unity").

12VAC5-481-3710. Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and

Manifests.

A. Manifest.

1. A waste generator, waste collector, or waste processor that transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a manifest reflecting information requested on applicable NRC Forms 540 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and 541 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, on an applicable NRC Form 542 (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation)). NRC Forms 540 and 540A must be completed and must physically accompany the pertinent low-level waste shipment.

2. Upon agreement between shipper and consignee, NRC Forms 541, 541A, 542, and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms.

3. Licensees are not required by the agency, the NRC, or another agreement state to comply with the manifesting requirements of this subpart when they ship:

a. Low-level radioactive waste for processing and expect its return, such as for storage under their license, prior to disposal at a licensed land disposal facility;

b. Low-level radioactive waste that is being returned to the licensee that is the waste generator or generator; or

c. Radioactively contaminated material to a waste processor that becomes the processor's residual waste.

4. For guidance in completing the forms required under subdivision 1 of this subsection, refer to the instructions that accompany the forms. Copies of manifests required by this subpart may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.

5. NRC Forms 540, 540A, 541, 541A, 542, and 542A, and the accompanying instructions, in hard copy, may be obtained by writing or calling the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (800) 368-5642, or by visiting the NRC's website at www.nrc.gov.

6. This section includes information requirements of the DOT, as codified in 49 CFR Part 172. Information on hazardous, medical, or other waste, required to meet Environmental Protection Agency (EPA) regulations, as codified in 40 CFR Part 259, 261 or elsewhere, is not addressed in this section and must be provided on the required EPA forms. However, the required EPA forms must accompany the uniform low-level radioactive waste manifest required by this section.

B. General information. The shipper of the radioactive waste must provide the following information on the uniform manifest:

1. The name, facility address, and telephone number of the licensee shipping the waste;

2. An explicit declaration indicating whether the shipper is acting as a waste generator, waste collector, waste processor, or a combination of these identifiers for purposes of the manifested shipment; and

3. The name, address, and telephone number, or the name and EPA identification number for the carrier transporting the waste.

C. Shipment information. The shipper of the radioactive waste must provide the following information regarding the waste shipment on the uniform manifest:

1. The date of the waste shipment;

2. The total number of packages or disposal containers;

3. The total disposal volume and disposal weight in the shipment;

4. The total radionuclide activity in the shipment;

5. The activity of each of the radionuclides H-3, C-14, Tc-99, and I-129 contained in the shipment; and

6. The total masses of U-233, U-235, and plutonium in special nuclear material and the total mass of uranium and thorium in source material.

D. Disposal container and waste information. The shipper of the radioactive waste must provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

1. An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

2. A physical description of the disposal container, including the manufacturer and model of any high integrity container;

3. The volume displaced by the disposal container;

4. The gross weight of the disposal container, including the waste;

5. For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

6. A physical and chemical description of the waste;

7. The total weight percentage of chelating agent for any waste containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

8. The approximate volume of waste within a container;

9. The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;

10. The identities and activities of individual radionuclides contained in each container,

the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types, such as activated materials, contaminated equipment, mechanical filters, sealed source or devices, and wastes in solidification or stabilization media, the identities and activities of individual radionuclides associated with or contained on these waste types within a disposal container must be reported; and

11. The total radioactivity within each container.

E. Uncontainerized waste information. The shipper of the radioactive waste must provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

1. The approximate volume and weight of the waste;

2. A physical and chemical description of the waste;

3. The total weight percentage of chelating agent if the chelating agent exceeds 0.1% by weight, plus the identity of the principal chelating agent;

4. For waste consigned to a disposal facility, the classification of the waste according to 12VAC5-481-2571 . Waste not meeting the structural stability requirements of 12VAC5-481-2572 must be identified;

5. The identities and activities of individual radionuclides contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

6. For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

F. Multigenerator disposal container information.

1. This subsection applies to disposal containers enclosing mixtures of waste originating from different generators. The origin of the low-level radioactive waste resulting from a waste processor's activities may be attributable to one or more generators, including waste generators. This subsection also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

2. For homogeneous mixtures of waste, such as incinerator ash, the shipper must provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

3. For heterogeneous mixtures of waste, such as the combined products from a large compactor, the shipper must identify each generator contributing waste to the disposal container and for discrete waste types, such as activated materials, contaminated equipment, mechanical filters, sealed source or devices, and wastes in solidification or stabilization media, the identities and activities of individual radionuclides contained on these waste types within the disposal container. For each generator, the shipper must

provide the following:

a. The volume of waste within the disposal container;

b. A physical and chemical description of the waste, including the solidification agent, if any;

c. The total weight percentage of chelating agents for any disposal container containing more than 0.1 percent chelating agent by weight, plus the identity of the principal chelating agent;

d. The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in 12VAC5-481-2572; and

e. Radionuclide identities and activities contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material, if contained in the waste.

G. Certification. An authorized representative of the waste generator, waste processor, or waste collector must certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the DOT and the agency, NRC or another agreement state. A waste collector, in signing the certification, is certifying that nothing has been done to the collected waste that would invalidate the waste generator's certification.

H. Control and tracking; transfers. A licensee that transfers radioactive waste to a land disposal facility or a licensed waste collector must comply with subdivisions 1 through 9 of this subsection. A licensee that transfers waste to a licensed waste processor for waste treatment or repackaging must comply with subdivisions 4 through 9 of this subsection. A licensee shall:

1. Prepare all wastes so that the waste is classified according to 12VAC5-481-2571 , and meets the waste characteristics requirements in 12VAC5-481-2572;

2. Label each disposal container of waste, or transport package if potential radiation hazards preclude labeling of the individual disposal container, to identify whether it is Class A waste, Class B waste, Class C waste, or greater than Class C waste, according to 12VAC5-481-2571;

3. Conduct a quality assurance program to ensure compliance with 12VAC5-481-2571 and 12VAC5-481-2572 . The program must include management evaluation of audits;

4. Prepare the uniform low-level radioactive waste manifest as required by this part;

5. Forward a copy or electronically transfer the uniform low-level radioactive waste manifest to the intended consignee so that receipt of the manifest precedes the low-level radioactive waste shipment or the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee, or both;

6. Include NRC Form 540, and Form 540A if required, with the shipment regardless of the option chosen in subdivision 5 of this subsection;

7. Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540;

8. Retain a copy of or electronically store the uniform low-level radioactive waste manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by Part I (12VAC5-481-10 et seq.), Part III (12VAC5-481-380 et seq.), Part IV (12VAC5-481-600 et seq.) and Part X (12VAC5-481-2250 et seq.); and

9. For any shipment or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this part, conduct an investigation according to subsection L of this section.

I. Control and tracking; prepackaged waste. A waste collector licensee that handles only prepackaged waste must:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of NRC Form 540;

2. Prepare a new manifest to reflect consolidated shipments that meet the requirements of this section. The waste collector must ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;

3. Forward a copy or electronically transfer the uniform low-level radioactive waste manifest to the intended consignee so that receipt of the manifest precedes the low-level radioactive waste shipment or the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee, or both;

4. Include NRC Form 540, and 540A if required, with the shipment regardless of the option chosen in subdivision 4 of this subsection;

5. Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540;

6. Retain a copy of or electronically store the uniform low-level radioactive waste manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required under Part I (12VAC5-481-10 et seq.), Part III (12VAC5-481-380 et seq.), Part IV (12VAC5-481-600 et seq.) and Part X (12VAC5-481-2250 et seq.);

7. For any shipment or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this section, conduct an investigation according to subsection L of this section; and

8. Notify the shipper and the agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

J. Control and tracking; treatment or repackaging. A licensed waste processor that treats or

repackages waste must:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of NRC Form 540;

2. Prepare a new manifest that meets the requirements of this section. Preparation of the new manifest reflects that the waste processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest must identify the waste generators, the preprocessed waste volume, and the other information as required under subsection F of this section;

3. Prepare all wastes so that the waste is classified according to 12VAC5-481-2571 , and meets the waste characteristics requirements in 12VAC5-481-2572;

4. Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with 12VAC5-481-2571 and 12VAC5-481-2572;

5. Conduct a quality assurance program to ensure compliance with 12VAC5-481-2571 and 12VAC5-481-2572 . The program must include management evaluation of audits;

6. Forward a copy or electronically transfer the uniform low-level radioactive waste manifest to the intended consignee so that receipt of the manifest precedes the low-level radioactive waste shipment or the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee, or both;

7. Include NRC Form 540, and Form 540A if required, with the shipment regardless of the option chosen in subdivision 6 of this subsection;

8. Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540;

9. Retain a copy of or electronically store the uniform low-level radioactive waste manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by Part I (12VAC5-481-10 et seq.), Part III (12VAC5-481-380 et seq.), Part IV (12VAC5-481-600 et seq.) and Part X (12VAC5-481-2250 et seq.);

10. For any shipment or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this part, conduct an investigation according to subsection L; and

11. Notify the shipper and the agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

K. Control and tracking; land disposal facility. A land disposal facility operator shall:

1. Acknowledge receipt of the waste within one week of receipt by returning, as a minimum, a signed copy of NRC Form 540 to the shipper. The shipper to be notified is the licensee that last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the uniform low-level radioactive waste

manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;

2. Maintain copies of all completed manifests and electronically store the information required by 12VAC5-481-2630 , until the agency terminates the license; and

3. Notify the shipper and the agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

L. Investigation. A shipment or part of a shipment for which acknowledgment is not received within the times set forth in this part must:

1. Be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

2. Be traced and reported. The investigation must include tracing the shipment and filing a report with the agency. A licensee that conducts a trace investigation must file a written report with the agency within two weeks of completing the investigation.

12VAC5-481-3720. Exempt Concentrations Schedule.

Element (atomic number)	Isotope	Col. I	Col. II
		Gas Concentration µCi/ml[1]	Liquid and Solid Concentration µCi/ml[2]
Antimony (51)	Sb-122		3×10^{-4}
	Sb-124		2×10^{-4}
	Sb-125		1×10^{-3}
Argon (18)	A-37	1×10^{-3}	
	A-41	4×10^{-7}	
Arsenic (33)	As-73		5×10^{-3}
	As-74		5×10^{-4}
	As-76		2×10^{-4}
	As-77		8×10^{-4}
Barium (56)	Ba-131		2×10^{-3}
	Ba-140		3×10^{-4}
Beryllium (4)	Be-7		2×10^{-2}
Bismuth (83)	Bi-206		

			4×10^{-4}
Bromine (35)	Br-82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd-109		2×10^{-3}
	Cd-115M		3×10^{-4}
	Cd-115		3×10^{-4}
Calcium (20)	Ca-45		9×10^{-5}
	Ca-47		5×10^{-4}
Carbon (6)	C-14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce-141		9×10^{-4}
	Ce-143		4×10^{-4}
	Ce-144		1×10^{-4}
Cesium (55)	Cs-131		2×10^{-2}
	Cs-134m		6×10^{-2}
	Cs-134		9×10^{-5}
Chlorine (17)	Cl-38	9×10^{-7}	4×10^{-3}
Chromium (24)	Cr-51		2×10^{-2}
Cobalt (27)	Co-57		5×10^{-3}
	Co-58		1×10^{-3}
	Co-60		5×10^{-4}
Copper (29)	Cu-64		3×10^{-3}
Dysprosium (66)	Dy-165		4×10^{-3}
	Dy-166		4×10^{-4}
Erbium (68)	Er-169		9×10^{-4}
	Er-171		1×10^{-3}
Europium (63)	Eu-152 (9.2 hrs)		6×10^{-4}
	Eu-155		2×10^{-3}

Fluorine (9)	F-18	2×10^{-6}	8×10^{-3}
Gadolinium (64)	Gd-153		2×10^{-3}
	Gd-159		8 x `0^{-4}
Gallium (31)	Ga-72		4×10^{-4}
Germanium (32)	Ge-71		2×10^{-2}
Gold (79)	Au-196		2×10^{-3}
	Au-198		5×10^{-4}
	Au-199		2×10^{-3}
Hafnium (72)	Hf-81		7×10^{-4}
Hydrogen (1)	H-3	5×10^{-6}	3×10^{-2}
Indium (49)	In-113M		1×10^{-2}
	In-114M		2×10^{-4}
Iodine (53)	I-126	3×10^{-9}	2×10^{-5}
	I-131	3×10^{-9}	2×10^{-5}
	I-132	8×10^{-8}	6×10^{-4}
	I-133	1×10^{-8}	7×10^{-5}
	I-134	2×10^{-7}	1×10^{-3}
Iridium (77)	Ir-190		2×10^{-3}
	Ir-192		4×10^{-4}
	Ir-194		3×10^{-4}
Iron (26)	Fe-55		8×10^{-3}
	Fe-59		6×10^{-4}
Krypton (36)	Kr-85M	1×10^{-6}	
	Kr-85	3×10^{-6}	
Lanthanum (57)	La-140		2×10^{-4}
Lead (82)	Pb-203		4×10^{-3}
Lutetium (71)	Lu-177		1×10^{-3}

Manganese (25)	Mn-52		3×10^{-4}
	Mn-54		1×10^{-3}
	Mn-56		1×10^{-3}
Mercury (80)	Hg-197M		2×10^{-3}
	Hg-197		3×10^{-3}
	Hg-203		2×10^{-4}
Molybdenum (42)	Mo-99		2×10^{-3}
Neodymium (60)	Nd-147		6×10^{-4}
	Nd-149		3×10^{-3}
Nickel (28)	Ni-65		1×10^{-3}
Niobium (Columbium) (41)	Nb-95		1×10^{-3}
	Nb-97		9×10^{-3}
Osmium (76)	Os-185		7×10^{-4}
	Os-191M		3×10^{-2}
	Os-191		2×10^{-3}
	Os-193		6×10^{-4}
Palladium (46)	Pd-103		3×10^{-3}
	Pd-109		9×10^{-4}
Phosphorus (15)	P-32		2×10^{-4}
Platinum (78)	Pt-191		1×10^{-3}
	Pt-193M		1×10^{-2}
	Pt-197M		1×10^{-2}
	Pt-197		1×10^{-3}
Potassium (19)	K-42		3×10^{-3}
Praseodymium (59)	Pr-142		3×10^{-4}
	Pr-143		5×10^{-4}
Promethium (61)	Pm-147		2×10^{-3}

	Pm-149		4×10^{-4}
Rhenium (75)	Re-183		6×10^{-3}
	Re-186		9×10^{-4}
	Re-188		6×10^{-4}
Rhodium (45)	Rh-103M		1×10^{-1}
	Rh-105		1×10^{-3}
Rubidium (37)	Rb-86		7×10^{-4}
Ruthenium (44)	Ru-97		4×10^{-4}
	Ru-103		8×10^{-4}
	Ru-105		1×10^{-3}
	Ru-106		1×10^{-4}
Samarium (62)	Sm-153		8×10^{-4}
Scandium (21)	Sc-46		4×10^{-4}
	Sc-47		9×10^{-4}
	Sc-48		3×10^{-4}
Selenium (34)	Se-75		3×10^{-3}
Silicon (14)	Si-31		9×10^{-3}
Silver (47)	Ag-105		1×10^{-3}
	Ag-110M		3×10^{-4}
	Ag-111		4×10^{-4}
Sodium (11)	Na-24		2×10^{-3}
Strontium (38)	Sr-85		1×10^{-4}
	Sr-89		1×10^{-4}
	Sr-91		7×10^{-4}
	Sr-92		7×10^{-4}
Sulfur (16)	S-35	9×10^{-8}	6×10^{-4}
Tantalum (73)	Ta-182		4×10^{-4}

Technetium (43)	Tc-96M		1×10^{-1}
	Tc-96		1×10^{-3}
Tellurium (52)	Te-125M		2×10^{-3}
	Te-125M		6×10^{-4}
	Te-127		3×10^{-3}
	Te-129M		3×10^{-4}
	Te-131M		6×10^{-4}
	Te-132		3×10^{-4}
Terbium (65)	Tb-160		4×10^{-4}
Thallium (81)	Tl-200		4×10^{-3}
	Tl-201		3×10^{-3}
	Tl-202		1×10^{-3}
	Tl-204		1×10^{-3}
Thulium (69)	Tm-170		5×10^{-4}
	Tm-171		5×10^{-3}
Tin (50)	Sn-113		9×10^{-4}
	Sn-125		2×10^{-4}
Tungsten (Wolfram) (74)	W-181		4×10^{-3}
	W-187		7×10^{-4}
Vanadium (23)	V-48		3×10^{-4}
Xenon (54)	Xe-131M	4×10^{-6}	
	Xe-133	3×10^{-6}	
	Xe-135	1×10^{-6}	
Ytterbium (70)	Yb-175		1×10^{-3}
Yttrium (39)	Y-90		2×10^{-4}
	Y-91M		3×10^{-2}
	Y-91		3×10^{-4}

	Y-92 Y-93		6×10^{-4} 3×10^{-4}
Zinc (30)	Zn-65 Zn-69M Zn-69		1×10^{-3} 7×10^{-4} 2×10^{-2}
Zirconium (40)	Zr-95 Zr-97		6×10^{-4} 2×10^{-4}
Beta and/or gamma emitting radioactive material not listed above with half-life less than three years		1×10^{-10}	1×10^{-6}
Footnotes: [1]Values are given only for those materialsnormally used as gases. [2]μCi/gm for solids.			

NOTE 1: Many radioisotopes disintegrate into isotopes that are also radioactive. In expressing the concentrations, the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of 12VAC5-481-400 A where there is involved a combination of isotopes, the limit for the combination should be derived as follows:

Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

Example:

$$\frac{\text{Concentration of Isotope A in product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in product}}{\text{Exempt concentration of Isotope B}} \leq 1$$

12VAC5-481-3730. Exempt Quantities.

Radioactive material	Microcuries
Antimony 122 (Sb 122)	100
Antimony 124 (Sb 124)	10
Antimony 125 (Sb 125)	10
Arsenic 73 (As 73)	100
Arsenic 74 (As 74)	10

Arsenic 76 (As 76)	10
Arsenic 77 (as 77)	100
Barium 131 (Ba 131)	10
Barium 133 (Ba 133)	10
Barium 140 (Ba 140)	10
Bismuth 210 (Bi 210)	1
Bromine 82 (Br 82)	10
Cadmium109 (Cd 109)	10
Cadmium 115m (Cd 115m)	10
Cadmium115 (Cd 115)	100
Calcium 45 (Ca 45)	10
Calcium 47 (Ca 47)	10
Carbon 14 (C 14)	100
Cerium 141 (Ce 141)	100
Cerium 143 (Ce 143)	100
Cerium 144 (Ce 144)	1
Cesium 129 (Cs 129)	100
Cesium 131 (Cs 131)	1,000
Cesium 134m (Cs 134m)	100
Cesium 134 (Cs 134)	1
Cesium 135 (Cs 135)	10
Cesium 136 (Cs 136)	10
Cesium 137 (Cs 137)	10
Chlorine 36 (Cl 36)	10
Chlorine 38 (Cl 38)	10
Chromium 51 (Cr 51)	1,000
Cobalt 57 (Co 57)	100
Cobalt 58m (Co 58m)	10
Cobalt 58 (Co 58)	10

Cobalt 60 (Co 60)	1
Copper 64 (Cu 64)	100
Dysprosium 165 (Dy 165)	10
Dysprosium 166(Dy 166)	100
Erbium 169 (Er 169)	100
Erbium 171 (Er 171)	100
Europium 152 9.2 h (Eu 152 9.2 h)	100
Europium 152 13 yr (Eu 152 13 yr)	1
Europium 154 (Eu 154)	1
Europium 155(Eu 155)	10
Fluorine 18 (F 18)	1,000
Gadolinium 153 (Gd 153)	10
Gadolinium 159 (Gd 159)	100
Gallium 67 (Ga 67)	100
Gallium 72 (Ga 72)	10
Germanium 68 (Ge 68)	10
Germanium 71 (Ga 71)	100
Gold 195 (Au 195)	10
Gold 198 (Au 198)	100
Gold 199 (Au 199)	100
Hafnium 181 (Hf 181)	10
Holmium 166 (Ho 166)	100
Hydrogen 3 (H3)	1,000
Indium 111 (In 111)	100
Indium 113m (In 113m)	100
Indium 114m(In 114m)	10
Indium 115m(In 115m)	100
Indium 115 (In 115)	10
Iodine 123 (I 123)	100

Iodine 125 (I 125)	1
Iodine 126 (I 126)	1
Iodine 129 (I 129)	0,1
Iodine 131 (I 131)	1
Iodine 132 (I 132)	10
Iodine 133 (I 133)	1
Iodine 134 (I 134)	10
Iodine 135 (I 135)	10
Iridium 192 (Ir 192)	10
Iridium 194 (Ir 194)	100
Iron 52 (Fe 52)	10
Iron 55 (Fe 55)	100
Iron 59 (Fe 59)	10
Krypton 85 (Kr 85)	100
Krypton 87 (Kr 87)	10
Lanthanum 140 (La 140)	10
Lutetium 177 (Lu 177)	100
Manganese 52 (Mn 52)	10
Manganese 54 (Mn 54)	10
Manganese 56 (Mn 56)	10
Mercury 197m (Hg 197m)	100
Mercury 197 (Hg 197)	100
Mercury 203 (Hg 203)	10
Molybdenum 99 (Mo 99)	100
Neodymium 147 (Nd 147)	100
Neodymium 149 (Nd 149)	100
Nickel 59 (Ni 59)	100
Nickel 63 (Ni 63)	10
Nickel 65 (Ni 65)	100

Niobium 93m (Nb 93m)	10
Niobium 95 (Nb 95)`	10
Niobium 97 (Nb 97)	10
Osmium 185 (Os 185)	10
Osmium 191m (Os 191)	100
Osmium 191 (Os 191)	100
Osmium 193 (Os 193)	100
Palladium 103 (Pd 103)	100
Palladium 109(Pd 109)	100
Phosphorus 32 (P 32)	10
Platinum 191 (Pt 191)	100
Platinum 193m(Pt 193m)	100
Platinum 193 (Pt 193)	100
Platinum 197m(Pt 197m)	100
Platinum 197 (Pt 197)	100
Polonium 210 (Po 210)	0.1
Potassium 42 (K 42)	10
Potassium 43 (K 43)	10
Praseodymium 142 (Pr 142)	100
Praseodymium 143 (Pr 143)	100
Promethium 147 (Pm 147)	10
Promethium 149 (Pm 149)	10
Rhenium 186 (Re 186)	100
Rhenium 188 (Re 188)	100
Rhodium 103m (Rh 103m)	100
Rhodium 105 (Rh 105)	100
Rubidium 81 (Rb81)	10
Rubidium 86 (R86)	10
Rubidium 87 (Rb87)	10

Ruthenium 97 (Ru 97)	100
Ruthenium 103 (Ru 103)	10
Ruthenium 105(Ru 105)	10
Ruthenium 106(Ru 106)	1
Samarium 151(Sm 151)	10
Samarium 153(Sm 153)	100
Scandium 46 (Sc 46)	10
Scandium 47 (Sc 47)	100
Scandium 48 (Sc 48)	10
Selenium 75 (Se 75)	10
Silicon 31 (Si 31)	100
Silver 105 (Ag 105)	10
Silver 110m (Ag 110m)	1
Silver 111 (Ag 111)	100
Sodium 22 (Na 22)	10
Sodium 24 (Na 24)	10
Strontium 85 (Sr 85)	10
Strontium 89 (Sr 89)	1
Strontium 90 (Sr 90)	0.1
Strontium 91 (Sr 91)	10
Strontium 92 (Sr 92)	10
Sulphur 35 (S 35)	100
Tantalum 182 (Ta 182)	10
Technetium 96 (Tc 96)	10
Technetium 97m (Tc 97m)	100
Technetium 97 (Tc 97)	100
Technetium 99m (Tc 99m)	100
Technetium 99 (Tc 99)	10
Tellurium 125 m (Te 125 m)	10

Tellurium 127m (Te 127m)	10
Tellurium 127 (Te 127)	100
Tellurium 129m (Te 129m)	10
Tellurium 129 (Te 129)	100
Tellurium 131m (Te 131m)	10
Tellurium 132 (Te 132)	10
Terbium 160 (Tb 160)	10
Thallium 200 (Tl 200)	100
Thallium 201 (Tl 201)	100
Thallium 202 (Tl 202)	100
Thallium 204 (Tl 204)	10
Thulium 170 (Tm 170)	10
Thulium 171 (Tm 171)	10
Tin 113 (Sn 113)	10
Tin 125 (Sn 125)	10
Tungsten 181 (W 181)	10
Tungsten 185 (W 185)	10
Tungsten 187 (W 187)	100
Vanadium 48 (V 48)	10
Xenon 131m (Xe 131m)	1,000
Xenon 133 (Xe 133)	100
Xenon 135 (Xe 135)	100
Ytterbium 175 (Yb 175)	100
Yttrium 87 (Y 87)	10
Yttrium 88 (Y 88)	10
Yttrium 90 (Y 90)	10
Yttrium 91 (Y91)	10
Yttrium 92 (Y92)	100
Yttrium 93 (Y93)	100

Zinc 65 (Zn 65)	10
Zinc 69m (Zn 69m)	100
Zinc 69 (Zn 69)	1,000
Zirconium 93 (Zr 93)	10
Zirconium 95 (Zr 95)	10
Zirconium 97 (Zr 97)	10
Any radioactive material not listed above other than alpha emitting radioactive materials	0.1

12VAC5-481-3740. Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release.

Radioactive material[1]	Release fraction	Quantity (curies)
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	g (20 mg)
Carbon-14 (non-carbon dioxide)	.01	50,000
Cerium-141	.01	10,000
Cerium-144	.01	300

Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000
Gadolinium-153	.01	5,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114m	.01	1,000
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000

Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Radium-226	.001	100
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technitium-99	.01	10,000
Technitium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000

Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma[2]	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha[2]	.0001	20
Combinations of radioactive materials listed above[1]		
[1]For combinations of radioactive materials, considerationof the need for an emergency plan is required if the sum of the ratios of thequantity of each radioactive material authorized to the quantity listed forthat material in this section exceeds one.		

[2]Waste packaged in Type B containers does notrequire an emergency plan.

12VAC5-481-3750. Quantities for Use with Decommissioning.

Materials	Microcuries
Americium-241	.01
Antimony-122	100
Antimony-124	10
Antimony-125	10
Arsenic-73	100
Arsenic-74	10
Arsenic-76	10
Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115m	10
Cadmium-115	100
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000
Cesium-134m	100
Cesium-134	1

Cesium-135	10
Cesium-136	10
Cesium-137	10
Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-55	100
Cobalt-56	10
Cobalt-57	100
Cobalt-58m	10
Cobalt-58	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100
Erbium-169	100
Erbium-171	100
Europium-152 9.2h	100
Europium-152 13 yr	1
Europium-154	1
Europium-155	10
Fluorine-18	1,000
Gadolinium-153	10
Gadolinium-159	100
Gallium-72	10
Germanium-71	100

Gold-198	100
Gold-199	100
Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115m	100
Indium-115	10
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100
Krpton-87	10
Lanthanum-140	10
Lutetium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197m	100

Mercury-197	100
Mercury-203	10
Molbdenum-99	100
Neodymium-147	100
Neodymium-149	100
Nickel-59	100
Nickel-63	10
Nickel-65	100
Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10
Osmium-191m	100
Osmium-191	100
Osmium-193	100
Palladium-103	100
Palladium-109	100
Phosphorus-32	10
Platinum-191	100
Platinum-193m	100
Platinum-193	100
Platinum-197m	100
Platinum-197	100
Plutonium-239	.01
Polonium-210	0.1
Potassium-42	10

Praseodymium-142	100
Praseodymium-143	100
Promethium-147	10
Promethium-149	10
Radium-226	.01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-105	100
Rubidium-86	10
Rubidium-87	10
Ruthenium-97	100
Ruthenium-103	10
Ruthenium-105	10
Ruthenium-106	1
Samarium-151	10
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Seleium-75	10
Silicon-31	100
Silver-105	10
Silver-110m	1
Silver-111	100

Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.1
Strontium-91	10
Strontium-92	10
Sulphur-35	100
Tantalum-182	10
Technetium-96	10
Technetium-97m	100
Technetium-97	100
Technetium-99m	100
Technetium-99	10
Tellurium-125m	10
Tellurium127m	10
Tellurium-127	100
Tellurium129m	10
Tellurium-129	100
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100

Thallium-204	10
Throium (natural)[1]	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10
Tungsten-185	10
Tungsten-187	100
Uranium (natural)[2]	100
Uranium-233	.01
Uranium-234--Uranium-235	.01
Vandium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-175	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10
Any alpha	.01

emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	
Any radionuclide other than alpha emitting radio-nuclides, not listed above or mixtures of beta emitters of unknown composition	.1

[1]Based on alpha disintegration rate of Th-232, Th-230, and their daughter products.
[2]Based on alpha disintegration rate of U-238, U-234, and U-235.

Note: For purposes of 12VAC5-481-930 , where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows: Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1" (i.e., "unity").

12VAC5-481-3760. Limits for Broad Scopes.

Radioactive material	Col. I curies	Col. II curies
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01

Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1
Cesium-134m	100	1
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1
Chromium-51	100	1
Cobalt-57	10	0.1
Cobalt-58m	100	1
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1

Dysprosium-165	100	1
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 9.2 h	10	0.1
Europium-152 13 y	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1
Indium-113m	100	1
Indium-114m	1	0.01
Indium-115m	100	1
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1

Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Irion-59	1	0.01
Krypton-85	100	1
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutelium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1
Osmium-185	1	0.01
Osmium-191m	100	1
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1

Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1
Platinum-193	10	0.1
Platinum-197m	100	1
Platinum-197	100	.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-186	10	0.1
Rhenium-188	10	0.1
Rhodium-103m	1,000	10
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01

Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85m	1,000	10
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulphur-35	10	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurim-129	100	1
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1

Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-187	10	0.1
Vandadium-48	1	0.01
Xenon-131m	1,000	10
Xenon-133	100	1
Xenon-135	100	1
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01
Zinc-69m	10	0.1
Zinc-69	100	1
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radioactive material other than alpha emitting radioactive material not listed above	0.1	0.001

12VAC5-481-3770. Determination of a_1 and a_2.

A. Values of A_1 and A_2 for individual radionuclides, which are the bases for many activity limits elsewhere in these regulations, are given in Table 1 of this section. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) value. The terabecquerel values are the regulatory standard. The curie values are for information only and are not intended to be the regulatory standard. Where values of A_1 and A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

B. For individual radionuclides whose identities are known, but that are not listed in Table 1 or Table 2 of this section, the A_1 and A_2 values or exempt material activity concentration and exempt consignment activity values contained in Table 3 of this section may be used. Otherwise, the licensee shall obtain prior agency approval for radionuclides not listed in Table 1 or Table 2 of this section, before shipping the material. The licensee shall submit requests for prior approval to the agency.

C. In the calculations of A_1 and A_2 for a radionuclide not in Table 1 of this section, a single radioactive decay chain, in which radionuclides are present in their naturally occurring proportions, and in which no daughter radionuclide has a half-life either longer than 10 days, or longer than that of the parent radionuclide, shall be considered as a single radionuclide, and the activity to be taken into account, and the A_1 orA_2 value to be applied, shall be those corresponding to the parent radionuclide of that chain. In the case of radioactive decay chains in which any daughter radionuclide has a half-life either longer than 10 days or greater than that of the parent radionuclide, the parent and those daughter radionuclides shall be considered as mixtures of different radionuclides.

D. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:

1. For special form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} \leq 1$$

where B(i) is the activity of radionuclide (i), and A_1(i) is the A_1 value for radionuclide (i).

2. For normal form radioactive material, the maximum quantity transported in a Type A package is as follows:

B(i)/A2(i)1

where B(i) is the activity of radionuclide (i), and A_2(i) is the A_2 value for radionuclide (i) in special form.

3. Alternatively, the A_1 value for mixtures of special form material may be determined as follows:

$$A_1 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_1(i)}}$$

where f(i) is the fraction of activity for radionuclide (i) in the mixture, and $A_1(i)$ is the appropriate A_1 value for radionuclide (i).

4. Alternatively, the A_2 value for mixtures of normal form material may be determined as follows:

$$A_2 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_2(i)}}$$

where f(i) is the fraction of activity for radionuclide (i) in the mixture, and $A_2(i)$ is the appropriate A_2 value for radionuclide (i).

5. The exempt activity concentration for mixtures of nuclides may be determined as follows:

$$\text{Exempt activity concentration for mixture} = \frac{1}{\sum_i \frac{f(i)}{[A](i)}}$$

where f(i) is the fraction of activity concentration of radionuclide (i) in the mixture, and [A](i) is the activity concentration for exempt material containing radionuclide (i).

6. The activity limit for an exempt consignment for mixtures of radionuclides may be determined as follows:

$$\text{Exempt consignment activity limit for mixture} = \frac{1}{\sum_i \frac{f(i)}{A(i)}}$$

where f(i) is the fraction of activity of radionuclide (i) in the mixture, and [A](i) is the activity limit for exempt consignments for radionuclide (i).

E. When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped, and the lowest A_1 or A_2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas in subsection D of this section. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A_1 or A_2 values for the alpha emitters and beta/gamma emitters.

F. Table 1. A_1 and A_2 Values for Radionuclides.

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Ac-225 (a)	Actinium (89)	$8.0X10^{-1}$	$2.2X10^{-1}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.1X10^{3}$	$5.8X10^{4}$
Ac-227 (a)		$9.0X10^{-1}$	$2.4X10^{-1}$	$9.0X10^{-5}$	$2.4X10^{-3}$	2.7	$7.2X10^{1}$

Ac-228		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.4X10^{4}$	$2.2X10^{6}$
Ag-105	Silver (47)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
Ag-108m (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.7X10^{-1}$	$2.6X10^{1}$
Ag-110m (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.8X10^{2}$	$4.7X10^{3}$
Ag-111		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Al-26	Aluminum (13)	$1.0X10^{-1}$	2.7	$1.0X10^{-1}$	2.7	$7.0X10^{-4}$	$1.9X10^{-2}$
Am-241	Americium (95)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.3X10^{-1}$	3.4
Am-242m (a)		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.6X10^{-1}$	$1.0X10^{1}$
Am-243 (a)		5.0	$1.4X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.4X10^{-3}$	$2.0X10^{-1}$
Ar-37	Argon (18)	$4.0X10^{1}$	$1.1X10^{3}$	4.0X101	$1.1X10^{3}$	$3.7X10^{3}$	$9.9X10^{4}$
Ar-39		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	1.3	$3.4X10^{1}$
Ar-41		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	1.5X106	$4.2X10^{7}$
As-72	Arsenic (33)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$6.2X10^{4}$	$1.7X10^{6}$
As-73		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$8.2X10^{2}$	$2.2X10^{4}$
As-74		1.0	$2.7X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$3.7X10^{3}$	$9.9X10^{4}$
As-76		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$5.8X10^{4}$	$1.6X10^{6}$
As-77		$2.0X10^{1}$	$5.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.9X10^{4}$	$1.0X10^{6}$
At-211 (a)	Astatine (85)	$2.0X10^{1}$	$5.4X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$7.6X10^{4}$	$2.1X10^{6}$
Au-193	Gold (79)	7.0	$1.9X10^{2}$	2.0	$5.4X10^{1}$	$3.4X10^{4}$	$9.2X10^{5}$
Au-194		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.5X10^{4}$	$4.1X10^{5}$
Au-195		$1.0X10^{1}$	$2.7X10^{2}$	6.0	$1.6X10^{2}$	$1.4X10^{2}$	$3.7X10^{3}$
Au-198		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.0X10^{3}$	$2.4X10^{5}$
Au-199		$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$7.7X10^{3}$	$2.1X10^{5}$
Ba-131 (a)	Barium (56)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.1X10^{3}$	$8.4X10^{4}$

Ba-133		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	9.4	$2.6X10^{2}$
Ba-133m		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.2X10^{4}$	$6.1X10^{5}$
Ba-140 (a)		$5.0X10^{-1}$	1.4X101	$3.0X10^{-1}$	8.1	2.7X103	$7.3X10^{4}$
Be-7	Beryllium (4)	$2.0X10^{1}$	$5.4X10^{2}$	2.0X101	5.4X102	$1.3X10^{4}$	$3.5X10^{5}$
Be-10		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-1}$	$1.6X10^{1}$	$8.3X10^{-4}$	$2.2X10^{-2}$
Bi-205	Bismuth (83)	$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.5X10^{3}$	$4.2X10^{4}$
Bi-206		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$3.8X10^{3}$	$1.0X10^{5}$
Bi-207		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	1.9	$5.2X10^{1}$
Bi-210		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.6X10^{3}$	$1.2X10^{5}$
Bi-210m (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.1X10^{-5}$	$5.7X10^{-4}$
Bi-212 (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.4X10^{5}$	$1.5X10^{7}$
Bk-247	Berkelium (97)	8.0	$2.2X10^{2}$	$8.0X10^{-4}$	2.2X10-2	$3.8X10^{-2}$	1.0
Bk-249 (a)		$4.0X10^{1}$	1.1X103	$3.0X10^{-1}$	8.1	$6.1X10^{1}$	$1.6X10^{3}$
Br-76	Bromine (35)	$4.0X10^{-1}$	1.1X101	$4.0X10^{-1}$	$1.1X10^{1}$	$9.4X10^{4}$	$2.5X10^{6}$
Br-77		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$2.6X10^{4}$	$7.1X10^{5}$
Br-82		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{4}$	$1.1X10^{6}$
C-11	Carbon (6)	1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.1X10^{7}$	$8.4X10^{8}$
C-14		$4.0X10^{1}$	$1.1X10^{3}$	3.0	$8.1X10^{1}$	$1.6X10^{-1}$	4.5
Ca-41	Calcium (20)	Unlimited	Unlimited	Unlimited	Unlimited	$3.1X10^{-3}$	$8.5X10^{-2}$
Ca-45		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$6.6X10^{2}$	$1.8X10^{4}$
Ca-47 (a)		3.0	$8.1X10^{1}$	$3.0X10^{-1}$	8.1	$2.3X10^{4}$	$6.1X10^{5}$
Cd-109	Cadmium (48)	$3.0X10^{1}$	$8.1X10^{2}$	2.0	$5.4X10^{1}$	$9.6X10^{1}$	$2.6X10^{3}$
Cd-113m		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	8.3	$2.2X10^{2}$
Cd-115 (a)		3.0	$8.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.9X10^{4}$	$5.1X10^{5}$
Cd-115m		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$9.4X10^{2}$	$2.5X10^{4}$

Ce-139	Cerium (58)	7.0	$1.9X10^{2}$	2.0	$5.4X10^{1}$	$2.5X10^{2}$	$6.8X10^{3}$
Ce-141		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.1X10^{3}$	$2.8X10^{4}$
Ce-143		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{4}$	$6.6X10^{5}$
Ce-144 (a)		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.2X10^{2}$	$3.2X10^{3}$
Cf-248	Californium (98)	$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$5.8X10^{1}$	$1.6X10^{3}$
Cf-249		3.0	$8.1X10^{1}$	$8.0X10^{-4}$	$2.2X10^{-2}$	$1.5X10^{-1}$	4.1
Cf-250		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	4.0	$1.1X10^{2}$
Cf-251		7.0	$1.9X10^{2}$	$7.0X10^{-4}$	$1.9X10^{-2}$	$5.9X10^{-2}$	1.6
Cf-252 (h)		$5.0X10^{-2}$	1.4	$3.0X10^{-3}$	$8.1X10^{-2}$	$2.0X10^{1}$	$5.4X10^{2}$
Cf-253 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{-2}$	1.1	$1.1X10^{3}$	$2.9X10^{4}$
Cf-254		$1.0X10^{-3}$	$2.7X10^{-2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.1X10^{2}$	$8.5X10^{3}$
Cl-36	Chlorine (17)	$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{-3}$	$3.3X10^{-2}$
Cl-38		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$4.9X10^{6}$	$1.3X10^{8}$
Cm-240	Curium (96)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$7.5X10^{2}$	$2.0X10^{4}$
Cm-241		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$6.1X10^{2}$	$1.7X10^{4}$
Cm-242		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-2}$	$2.7X10^{-1}$	$1.2X10^{2}$	$3.3X10^{3}$
Cm-243		9.0	$2.4X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.9X10^{-3}$	$5.2X10^{4}$
Cm-244		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	3.0	$8.1X10^{1}$
Cm-245		9.0	$2.4X10^{2}$	$9.0X10^{-4}$	$2.4X10^{-2}$	$6.4X10^{-3}$	$1.7X10^{-1}$
Cm-246		9.0	$2.4X10^{2}$	$9.0X10^{-4}$	$2.4X10^{-2}$	$1.1X10^{-2}$	$3.1X10^{-1}$
Cm-247 (a)		3.0	$8.1X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.4X10^{-6}$	$9.3X10^{-5}$
Cm-248		$2.0X10^{-2}$	$5.4X10^{-1}$	$3.0X10^{-4}$	$8.1X10^{-3}$	$1.6X10^{-4}$	$4.2X10^{-3}$
Co-55	Cobalt (27)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.1X10^{5}$	$3.1X10^{6}$
Co-56		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.1X10^{3}$	$3.0X10^{4}$
Co-57		1.0X101	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$3.1X10^{2}$	$8.4X10^{3}$
Co-58		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.2X10^{3}$	$3.2X10^{4}$

Co-58m		4.0X101	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$2.2X10^{5}$	$5.9X10^{6}$
Co-60		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.2X10^{1}$	$1.1X10^{3}$
Cr-51	Chromium (24)	3.0X101	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$3.4X10^{3}$	$9.2X10^{4}$
Cs-129	Cesium (55)	4.0	$1.1X10^{2}$	4.0	$1.1X10^{2}$	2.8X104	$7.6X10^{5}$
Cs-131		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$3.8X10^{3}$	$1.0X10^{5}$
Cs-132		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$5.7X10^{3}$	$1.5X10^{5}$
Cs-134		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.8X10^{1}$	$1.3X10^{3}$
Cs-134m		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{5}$	$8.0X10^{6}$
Cs-135		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$4.3X10^{-5}$	$1.2X10^{-3}$
Cs-136		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.7X10^{3}$	$7.3X10^{4}$
Cs-137 (a)		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	1.6X101	3.2	$8.7X10^{1}$
Cu-64	Copper (29)	6.0	$1.6X10^{2}$	1.0	$2.7X10^{1}$	$1.4X10^{5}$	$3.9X10^{6}$
Cu-67		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.8X10^{4}$	$7.6X10^{5}$
Dy-159	Dysprosium (66)	$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$2.1X10^{2}$	$5.7X10^{3}$
Dy-165		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{5}$	$8.2X10^{6}$
Dy-166 (a)		$9.0X10^{-1}$	$2.4X10^{1}$	$3.0X10^{-1}$	8.1	$8.6X10^{3}$	$2.3X10^{5}$
Er-169	Erbium (68)	$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$3.1X10^{3}$	$8.3X10^{4}$
Er-171		$8.0X10^{-1}$	$2.2X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$9.0X10^{4}$	$2.4X10^{6}$
Eu-147	Europium (63)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.4X10^{3}$	$3.7X10^{4}$
Eu-148		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.0X10^{2}$	$1.6X10^{4}$
Eu-149		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$3.5X10^{2}$	$9.4X10^{3}$
Eu-150 (short lived)		2.0	$5.4X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.1X10^{4}$	$1.6X10^{6}$
Eu-150 (long lived)		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.1X10^{4}$	$1.6X10^{6}$
Eu-152		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	6.5	$1.8X10^{2}$

Eu-152m		$8.0X10^{-1}$	$2.2X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$8.2X10^{4}$	$2.2X10^{6}$
Eu-154		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	9.8	$2.6X10^{2}$
Eu-155		$2.0X10^{1}$	$5.4X10^{2}$	3.0	$8.1X10^{1}$	$1.8X10^{1}$	$4.9X10^{2}$
Eu-156		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.0X10^{3}$	$5.5X10^{4}$
F-18	Fluorine (9)	1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.5X10^{6}$	9.5X107
Fe-52 (a)	Iron (26)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.7X10^{5}$	$7.3X10^{6}$
Fe-55		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$8.8X10^{1}$	$2.4X10^{3}$
Fe-59		$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$1.8X10^{3}$	$5.0X10^{4}$
Fe-60 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-1}$	5.4	$7.4X10^{-4}$	$2.0X10^{-2}$
Ga-67	Gallium (31)	7.0	$1.9X10^{2}$	3.0	$8.1X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$
Ga-68		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.5X10^{6}$	$4.1X10^{7}$
Ga-72		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{5}$	$3.1X10^{6}$
Gd-146 (a)	Gadolinium (64)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.9X10^{2}$	$1.9X10^{4}$
Gd-148		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	1.2	$3.2X10^{1}$
Gd-153		$1.0X10^{1}$	$2.7X10^{2}$	9.0	$2.4X10^{2}$	$1.3X10^{2}$	$3.5X10^{3}$
Gd-159		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.9X10^{4}$	$1.1X10^{6}$
Ge-68 (a)	Germanium (32)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.6X10^{2}$	$7.1X10^{3}$
Ge-71		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.8X10^{3}$	$1.6X10^{5}$
Ge-77		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.3X10^{5}$	$3.6X10^{6}$
Hf-172 (a)	Hafnium (72)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.1X10^{1}$	$1.1X10^{3}$
Hf-175		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$3.9X10^{2}$	$1.1X10^{4}$
Hf-181		2.0	$5.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.3X10^{2}$	$1.7X10^{4}$
Hf-182		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-6}$	$2.2X10^{-4}$
Hg-194 (a)	Mercury (80)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.3X10^{-1}$	3.5
Hg-195m (a)		3.0	$8.1X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$

Hg-197		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.2X10^{3}$	$2.5X10^{5}$
Hg-197m		$1.0X10^{1}$	$2.7X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.5X10^{4}$	$6.7X10^{5}$
Hg-203		5.0	$1.4X10^{2}$	1.0	$2.7X10^{1}$	$5.1X10^{2}$	$1.4X10^{4}$
Ho-166	Holmium (67)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.6X10^{4}$	$7.0X10^{5}$
Ho-166m		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.6X10^{-2}$	1.8
I-123	Iodine (53)	6.0	$1.6X10^{2}$	3.0	$8.1X10^{1}$	$7.1X10^{4}$	$1.9X10^{6}$
I-124		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$9.3X10^{3}$	$2.5X10^{5}$
I-125		$2.0X10^{1}$	$5.4X10^{2}$	3.0	$8.1X10^{1}$	$6.4X10^{2}$	$1.7X10^{4}$
I-126		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$2.9X10^{3}$	$8.0X10^{4}$
I-129		Unlimited	Unlimited	Unlimited	Unlimited	$6.5X10^{-6}$	$1.8X10^{-4}$
I-131		3.0	$8.1X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.6X10^{3}$	$1.2X10^{5}$
I-132		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.8X10^{5}$	$1.0X10^{7}$
I-133		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{4}$	$1.1X10^{6}$
I-134		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$9.9X10^{5}$	$2.7X10^{7}$
I-135 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.3X10^{5}$	$3.5X10^{6}$
In-111	Indium (49)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$1.5X10^{4}$	$4.2X10^{5}$
In-113m		4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$6.2X10^{5}$	$1.7X10^{7}$
In-114m (a)		$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.6X10^{2}$	$2.3X10^{4}$
In-115m		7.0	$1.9X10^{2}$	1.0	$2.7X10^{1}$	$2.2X10^{5}$	$6.1X10^{6}$
Ir-189 (a)	Iridium (77)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$1.9X10^{3}$	$5.2X10^{4}$
Ir-190		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.3X10^{3}$	$6.2X10^{4}$
Ir-192 (c)		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.4X10^{2}$	$9.2X10^{3}$
Ir-194		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$3.1X10^{4}$	$8.4X10^{5}$
K-40	Potassium (19)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.4X10^{-7}$	$6.4X10^{-6}$
K-42		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$2.2X10^{5}$	$6.0X10^{6}$

K-43		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{5}$	$3.3X10^{6}$
Kr-81	Krypton (36)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$7.8X10^{-4}$	$2.1X10^{-2}$
Kr-85		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$1.5X10^{1}$	$3.9X10^{2}$
Kr-85m		8.0	$2.2X10^{2}$	3.0	$8.1X10^{1}$	$3.0X10^{5}$	$8.2X10^{6}$
Kr-87		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.0X10^{6}$	$2.8X10^{7}$
La-137	Lanthanum (57)	$3.0X10^{1}$	$8.1X10^{2}$	6.0	$1.6X10^{2}$	$1.6X10^{-3}$	$4.4X10^{-2}$
La-140		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.1X10^{4}$	$5.6X10^{5}$
Lu-172	Lutetium (71)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{3}$	$1.1X10^{5}$
Lu-173		8.0	$2.2X10^{2}$	8.0	$2.2X10^{2}$	$5.6X10^{1}$	$1.5X10^{3}$
Lu-174		9.0	$2.4X10^{2}$	9.0	$2.4X10^{2}$	$2.3X10^{1}$	$6.2X10^{2}$
Lu-174m		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$2.0X10^{2}$	$5.3X10^{3}$
Lu-177		$3.0X10^{1}$	$8.1X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.1X10^{3}$	$1.1X10^{5}$
Mg-28 (a)	Magnesium (12)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.0X10^{5}$	$5.4X10^{6}$
Mn-52	Manganese (25)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.6X10^{4}$	$4.4X10^{5}$
Mn-53		Unlimited	Unlimited	Unlimited	Unlimited	$6.8X10^{-5}$	$1.8X10^{-3}$
Mn-54		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$2.9X10^{2}$	$7.7X10^{3}$
Mn-56		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$8.0X10^{5}$	$2.2X10^{7}$
Mo-93	Molybdenum (42)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	$4.1X10^{-2}$	1.1
Mo-99 (a) (i)		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.8X10^{4}$	$4.8X10^{5}$
N-13	Nitrogen (7)	$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	5.4X107	$1.5X10^{9}$
Na-22	Sodium (11)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.3X10^{2}$	$6.3X10^{3}$
Na-24		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$3.2X10^{5}$	$8.7X10^{6}$
Nb-93m	Niobium (41)	$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	8.8	$2.4X10^{2}$
Nb-94		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.9X10^{-3}$	$1.9X10^{-1}$

Nb-95		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.5X10^{3}$	$3.9X10^{4}$
Nb-97		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.9X10^{5}$	$2.7X10^{7}$
Nd-147	Neodymium (60)	6.0	$1.6X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{3}$	$8.1X10^{4}$
Nd-149		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$4.5X10^{5}$	$1.2X1^{07}$
Ni-59	Nickel (28)	Unlimited	Unlimited	Unlimited	Unlimited	$3.0X10^{-3}$	$8.0X10^{-2}$
Ni-63		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	2.1	$5.7X10^{1}$
Ni-65		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$7.1X10^{5}$	$1.9X10^{7}$
Np-235	Neptunium (93)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.2X10^{1}$	$1.4X10^{3}$
Np-236 (short-lived)		$2.0X10^{1}$	$5.4X10^{2}$	2.0	$5.4X10^{1}$	$4.7X10^{-4}$	$1.3X10^{-2}$
Np-236 (long-lived)		9.0X100	$2.4X10^{2}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$4.7X10^{-4}$	$1.3X10^{-2}$
Np-237		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	$2.6X10^{-5}$	$7.1X10^{-4}$
Np-239		7.0	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$8.6X10^{3}$	$2.3X10^{5}$
Os-185	Osmium (76)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$2.8X10^{2}$	$7.5X10^{3}$
Os-191		$1.0X10^{1}$	$2.7X10^{2}$	2.0	$5.4X10^{1}$	$1.6X10^{3}$	$4.4X10^{4}$
Os-191m		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$4.6X10^{4}$	$1.3X10^{6}$
Os-193		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{4}$	$5.3X10^{5}$
Os-194 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.1X10^{1}$	$3.1X10^{2}$
P-32	Phosphorus (15)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.1X10^{4}$	$2.9X10^{5}$
P-33		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Pa-230 (a)	Protactinium (91)	2.0	$5.4X10^{1}$	$7.0X10^{-2}$	1.9	$1.2X10^{3}$	$3.3X10^{4}$
Pa-231		4.0	$1.1X10^{2}$	$4.0X10^{-4}$	$1.1X10^{-2}$	$1.7X10^{-3}$	$4.7X10^{-2}$
Pa-233		5.0	$1.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$7.7X10^{2}$	$2.1X10^{4}$
Pb-201	Lead (82)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$6.2X10^{4}$	$1.7X10^{6}$

Pb-202		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	$1.2X10^{-4}$	$3.4X10^{-3}$
Pb-203		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$1.1X10^{4}$	$3.0X10^{5}$
Pb-205		Unlimited	Unlimited	Unlimited	Unlimited	$4.5X10^{-6}$	$1.2X10^{-4}$
Pb-210 (a)		1.0	$2.7X10^{1}$	$5.0X10^{-2}$	1.4	2.8	$7.6X10^{1}$
Pb-212 (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$2.0X10^{-1}$	5.4	$5.1X10^{4}$	$1.4X10^{6}$
Pd-103 (a)	Palladium (46)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$2.8X10^{3}$	$7.5X10^{4}$
Pd-107		Unlimited	Unlimited	Unlimited	Unlimited	$1.9X10^{-5}$	$5.1X10^{-4}$
Pd-109		2.0	$5.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$7.9X10^{4}$	$2.1X10^{6}$
Pm-143	Promethium (61)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$1.3X10^{2}$	$3.4X10^{3}$
Pm-144		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.2X10^{1}$	$2.5X10^{3}$
Pm-145		$3.0X10^{1}$	$8.1X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	5.2	$1.4X10^{2}$
Pm-147		$4.0X10^{1}$	$1.1X10^{3}$	2.0	$5.4X10^{1}$	$3.4X10^{1}$	$9.3X10^{2}$
Pm-148m (a)		$8.0X10^{-1}$	$2.2X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$7.9X10^{2}$	$2.1X10^{4}$
Pm-149		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Pm-151		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.7X10^{4}$	$7.3X10^{5}$
Po-210	Polonium (84)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$1.7X10^{2}$	$4.5X10^{3}$
Pr-142	Praseodymium (59)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.3X10^{4}$	$1.2X10^{6}$
Pr-143		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{3}$	$6.7X10^{4}$
Pt-188 (a)	Platinum (78)	1.0	$2.7X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$2.5X10^{3}$	$6.8X10^{4}$
Pt-191		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$8.7X10^{3}$	$2.4X10^{5}$
Pt-193		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	1.4	$3.7X10^{1}$
Pt-193m		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Pt-195m		$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.2X10^{3}$	$1.7X10^{5}$
Pt-197		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.2X10^{4}$	$8.7X10^{5}$

Pt-197m		$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.7X10^{5}$	$1.0X10^{7}$
Pu-236	Plutonium (94)	$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$2.0X10^{1}$	$5.3X10^{2}$
Pu-237		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$4.5X10^{2}$	$1.2X10^{4}$
Pu-238		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$6.3X10^{-1}$	$1.7X10^{1}$
Pu-239		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$2.3X10^{-3}$	$6.2X10^{-2}$
Pu-240		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$8.4X10^{-3}$	$2.3X10^{-1}$
Pu-241 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-2}$	1.6	3.8	$1.0X10^{2}$
Pu-242		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.5X10^{-4}$	$3.9X10^{-3}$
Pu-244 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$6.7X10^{-7}$	$1.8X10^{-5}$
Ra-223 (a)	Radium (88)	$4.0X10^{-1}$	$1.1X10^{1}$	$7.0X10^{-3}$	$1.9X10^{-1}$	$1.9X10^{3}$	$5.1X10^{4}$
Ra-224 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$5.9X10^{3}$	$1.6X10^{5}$
Ra-225 (a)		$2.0X10^{-1}$	5.4	$4.0X10^{-3}$	$1.1X10^{-1}$	$1.5X10^{3}$	$3.9X10^{4}$
Ra-226 (a)		$2.0X10^{-1}$	5.4	$3.0X10^{-3}$	$8.1X10^{-2}$	$3.7X10^{-2}$	1.0
Ra-228 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$1.0X10^{1}$	$2.7X10^{2}$
Rb-81	Rubidium (37)	2.0	$5.4X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{5}$	$8.4X10^{6}$
Rb-83 (a)		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$6.8X10^{2}$	$1.8X10^{4}$
Rb-84		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.8X10^{3}$	$4.7X10^{4}$
Rb-86		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{3}$	$8.1X10^{4}$
Rb-87		Unlimited	Unlimited	Unlimited	Unlimited	$3.2X10^{-9}$	$8.6X10^{-8}$
Rb(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$6.7X10^{6}$	$1.8X10^{8}$
Re-184	Rhenium (75)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$6.9X10^{2}$	$1.9X10^{4}$
Re-184m		3.0	$8.1X10^{1}$	1.0	$2.7X10^{1}$	$1.6X10^{2}$	$4.3X10^{3}$
Re-186		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$6.9X10^{3}$	$1.9X10^{5}$
Re-187		Unlimited	Unlimited	Unlimited	Unlimited	$1.4X10^{-9}$	$3.8X10^{-8}$
Re-188		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.6X10^{4}$	$9.8X10^{5}$
Re-189 (a)		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{4}$	$6.8X10^{5}$

Re(nat)		Unlimited	Unlimited	Unlimited	Unlimited	0.0	$2.4X10^{-8}$
Rh-99	Rhodium (45)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$
Rh-101		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$4.1X10^{1}$	$1.1X10^{3}$
Rh-102		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$4.5X10^{1}$	$1.2X10^{3}$
Rh-102m		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.3X10^{2}$	$6.2X10^{3}$
Rh-103m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$1.2X10^{6}$	$3.3X10^{7}$
Rh-105		$1.0X10^{1}$	$2.7X10^{2}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{4}$	$8.4X10^{5}$
Rn-222 (a)	Radon (86)	$3.0X10^{-1}$	8.1	$4.0X10^{-3}$	$1.1X10^{-1}$	$5.7X10^{3}$	$1.5X10^{5}$
Ru-97	Ruthenium (44)	5.0	$1.4X10^{2}$	5.0	$1.4X10^{2}$	$1.7X10^{4}$	$4.6X10^{5}$
Ru-103 (a)		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.2X10^{3}$	$3.2X10^{4}$
Ru-105		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{5}$	$6.7X10^{6}$
Ru-106 (a)		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.2X10^{2}$	$3.3X10^{3}$
S-35	Sulphur (16)	$4.0X10^{1}$	$1.1X10^{3}$	3.0	$8.1X10^{1}$	$1.6X10^{3}$	$4.3X10^{4}$
Sb-122	Antimony (51)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Sb-124		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$6.5X10^{2}$	$1.7X10^{4}$
Sb-125		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$3.9X10^{1}$	$1.0X10^{3}$
Sb-126		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.1X10^{3}$	$8.4X10^{4}$
Sc-44	Scandium (21)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.7X10^{5}$	$1.8X10^{7}$
Sc-46		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.3X10^{3}$	$3.4X10^{4}$
Sc-47		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.1X10^{4}$	$8.3X10^{5}$
Sc-48		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$5.5X10^{4}$	$1.5X10^{6}$
Se-75	Selenium (34)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$5.4X10^{2}$	$1.5X10^{4}$
Se-79		$4.0X10^{1}$	$1.1X10^{3}$	2.0	$5.4X10^{1}$	$2.6X10^{-3}$	$7.0X10^{-2}$
Si-31	Silicon (14)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.4X10^{6}$	$3.9X10^{7}$
Si-32		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	3.9	$1.1X10^{2}$

Sm-145	Samarium (62)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.8X10^{1}$	$2.6X10^{3}$
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	$8.5X10^{-1}$	$2.3X10^{-8}$
Sm-151		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.7X10^{-1}$	$2.6X10^{1}$
Sm-153		9.0	$2.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.6X10^{4}$	$4.4X10^{5}$
Sn-113 (a)	Tin (50)	4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$3.7X10^{2}$	$1.0X10^{4}$
Sn-117m		7.0	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$
Sn-119m		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$1.4X10^{2}$	$3.7X10^{3}$
Sn-121m (a)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	2.0	$5.4X10^{1}$
Sn-123		$8.0X10^{-1}$	$2.2X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{2}$	$8.2X10^{3}$
Sn-125		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{3}$	$1.1X10^{5}$
Sn-126 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.0X10^{-3}$	$2.8X10^{-2}$
Sr-82 (a)	Strontium (38)	$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$2.3X10^{3}$	$6.2X10^{4}$
Sr-85		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$8.8X10^{2}$	$2.4X10^{4}$
Sr-85m		5.0	$1.4X10^{2}$	5.0	$1.4X10^{2}$	$1.2X10^{6}$	$3.3X10^{7}$
Sr-87m		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$4.8X10^{5}$	$1.3X10^{7}$
Sr-89		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.1X10^{3}$	$2.9X10^{4}$
Sr-90 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	5.1	$1.4X10^{2}$
Sr-91 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.3X10^{5}$	$3.6X10^{6}$
Sr-92 (a)		1.0	$2.7X10^{1}$	$3.0X10^{-1}$	8.1	$4.7X10^{5}$	$1.3X10^{7}$
T(H-3)	Tritium (1)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.6X10^{2}$	$9.7X10^{3}$
Ta-178 (long-lived)	Tantalum (73)	1.0	$2.7X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$4.2X10^{6}$	$1.1X10^{8}$
Ta-179		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$4.1X10^{1}$	$1.1X10^{3}$
Ta-182		$9.0X10^{-1}$	$2.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.3X10^{2}$	$6.2X10^{3}$
Tb-157	Terbium (65)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.6X10^{-1}$	$1.5X10^{1}$

Tb-158		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$5.6X10^{-1}$	$1.5X10^{1}$
Tb-160		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{2}$	$1.1X10^{4}$
Tc-95m (a)	Technetium (43)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$8.3X10^{2}$	$2.2X10^{4}$
Tc-96		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.2X10^{4}$	$3.2X10^{5}$
Tc-96m (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.4X10^{6}$	$3.8X10^{7}$
Tc-97		Unlimited	Unlimited	Unlimited	Unlimited	$5.2X10^{-5}$	$1.4X10^{-3}$
Tc-97m		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$5.6X10^{2}$	$1.5X10^{4}$
Tc-98		$8.0X10^{-1}$	$2.2X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.2X10^{-5}$	$8.7X10^{-4}$
Tc-99		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.3X10^{-4}$	$1.7X10^{-2}$
Tc-99m		$1.0X10^{1}$	$2.7X10^{2}$	4.0	$1.1X10^{2}$	$1.9X10^{5}$	$5.3X10^{6}$
Te-121	Tellurium (52)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.4X10^{3}$	$6.4X10^{4}$
Te-121m		5.0	$1.4X10^{2}$	3.0	$8.1X10^{1}$	$2.6X10^{2}$	$7.0X10^{3}$
Te-123m		8.0	$2.2X10^{2}$	1.0	$2.7X10^{1}$	$3.3X10^{2}$	$8.9X10^{3}$
Te-125m		$2.0X10^{1}$	$5.4X10^{2}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.7X10^{2}$	$1.8X10^{4}$
Te-127		$2.0X10^{1}$	$5.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.8X10^{4}$	$2.6X10^{6}$
Te-127m (a)		$2.0X10^{1}$	$5.4X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.5X10^{2}$	$9.4X10^{3}$
Te-129		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$7.7X10^{5}$	$2.1X10^{7}$
Te-129m (a)		$8.0X10^{-1}$	$2.2X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
Te-131m (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{4}$	$8.0X10^{5}$
Te-132 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{4}$	$3.0X10^{5}$
Th-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-3}$	$1.4X10^{-1}$	$1.1X10^{3}$	$3.1X10^{4}$
Th-228 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.0X10^{1}$	$8.2X10^{2}$
Th-229		5.0	$1.4X10^{2}$	$5.0X10^{-4}$	$1.4X10^{-2}$	$7.9X10^{-3}$	$2.1X10^{-1}$
Th-230		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.6X10^{-4}$	$2.1X10^{-2}$

Th-231		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.0X10^{4}$	$5.3X10^{5}$
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	$4.0X10^{-9}$	$1.1X10^{-7}$
Th-234 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$8.6X10^{2}$	$2.3X10^{4}$
Th(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-9}$	$2.2X10^{-7}$
Ti-44 (a)	Titanium (22)	$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	6.4	$1.7X10^{2}$
Tl-200	Thallium (81)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$
Tl-201		$1.0X10^{1}$	$2.7X10^{2}$	4.0	$1.1X10^{2}$	$7.9X10^{3}$	$2.1X10^{5}$
Tl-202		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.0X10^{3}$	$5.3X10^{4}$
Tl-204		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.7X10^{1}$	$4.6X10^{2}$
Tm-167	Thulium (69)	7.0	$1.9X10^{2}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{3}$	$8.5X10^{4}$
Tm-170		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.2X10^{2}$	$6.0X10^{3}$
Tm-171		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$
U-230 (fast lung absorption) (a)(d)	Uranium (92)	$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-1}$	2.7	$1.0X10^{3}$	$2.7X10^{4}$
U-230 (medium lung absorption) (a)(e)		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{-3}$	$1.1X10^{-1}$	$1.0X10^{3}$	$2.7X10^{4}$
U-230 (slow lung absorption) (a)(f)		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$1.0X10^{3}$	$2.7X10^{4}$
U-232 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-2}$	$2.7X10^{-1}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-232 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$7.0X10^{-3}$	$1.9X10^{-1}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-232 (slow lung		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$8.3X10^{-1}$	$2.2X10^{1}$

absorption) (f)							
U-233 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-2}$	2.4	$3.6X10^{-4}$	$9.7X10^{-3}$
U-233 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$3.6X10^{-4}$	$9.7X10^{-3}$
U-233 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$3.6X10^{-4}$	$9.7X10^{-3}$
U-234 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-2}$	2.4	$2.3X10^{-4}$	$6.2X10^{-3}$
U-234 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.3X10^{-4}$	$6.2X10^{-3}$
U-234 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.3X10^{-4}$	$6.2X10^{-3}$
U-235 (all lung absorption types) (a),(d),(e),(f)		Unlimited	Unlimited	Unlimited	Unlimited	$8.0X10^{-8}$	$2.2X10^{-6}$
U-236 (fast lung absorption) (d)		Unlimited	Unlimited	Unlimited	Unlimited	$2.4X10^{-6}$	$6.5X10^{-5}$
U-236 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.4X10^{-6}$	$6.5X10^{-5}$
U-236		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.4X10^{-6}$	$6.5X10^{-5}$

(slow lung absorption) (f)							
U-238 (all lung absorption types) (d),(e),(f)		Unlimited	Unlimited	Unlimited	Unlimited	$1.2X10^{-8}$	$3.4X10^{-7}$
U (nat)		Unlimited	Unlimited	Unlimited	Unlimited	$2.6X10^{-8}$	$7.1X10^{-7}$
U (enriched to 20% or less) (g)		Unlimited	Unlimited	Unlimited	Unlimited	See Table A-4	See Table A-4
U (dep)		Unlimited	Unlimited	Unlimited	Unlimited	See Table A-4	See Table A-3
V-48	Vanadium (23)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$6.3X10^{3}$	$1.7X10^{5}$
V-49		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{2}$	$8.1X10^{3}$
W-178 (a)	Tungsten (74)	9.0	$2.4X10^{2}$	5.0	$1.4X10^{2}$	$1.3X10^{3}$	$3.4X10^{4}$
W-181		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$2.2X10^{2}$	$6.0X10^{3}$
W-185		$4.0X10^{1}$	$1.1X10^{3}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.5X10^{2}$	$9.4X10^{3}$
W-187		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.6X10^{4}$	$7.0X10^{5}$
W-188 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{-1}$	8.1	$3.7X10^{2}$	$1.0X10^{4}$
Xe-122 (a)	Xenon (54)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.8X10^{4}$	$1.3X10^{6}$
Xe-123		2.0	$5.4X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.4X10^{5}$	1.2X10
Xe-127		4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$1.0X10^{3}$	$2.8X10^{4}$
Xe-131m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.1X10^{3}$	$8.4X10^{4}$
Xe-133		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$6.9X10^{3}$	$1.9X10^{5}$
Xe-135		3.0	$8.1X10^{1}$	2.0	$5.4X10^{1}$	$9.5X10^{4}$	$2.6X10^{6}$
Y-87 (a)	Yttrium (39)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.7X10^{4}$	$4.5X10^{5}$
Y-88		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$5.2X10^{2}$	$1.4X10^{4}$
Y-90		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.0X10^{4}$	$5.4X10^{5}$

Y-91		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.1X10^{2}$	$2.5X10^{4}$
Y-91m		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.5X10^{6}$	4.2X10
Y-92		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$3.6X10^{5}$	$9.6X10^{6}$
Y-93		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.2X10^{5}$	$3.3X10^{6}$
Yb-169	Ytterbium (70)	4.0	$1.1X10^{2}$	1.0	$2.7X10^{1}$	$8.9X10^{2}$	$2.4X10^{4}$
Yb-175		$3.0X10^{1}$	$8.1X10^{2}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.6X10^{3}$	$1.8X10^{5}$
Zn-65	Zinc (30)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.0X10^{2}$	$8.2X10^{3}$
Zn-69		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.8X10^{6}$	4.9X10
Zn-69m (a)		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{5}$	$3.3X10^{6}$
Zr-88	Zirconium (40)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$6.6X10^{2}$	$1.8X10^{4}$
Zr-93		Unlimited	Unlimited	Unlimited	Unlimited	9.3X10	2.5X10
Zr-95 (a)		2.0	$5.4X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$7.9X10^{2}$	$2.1X10^{4}$
Zr-97 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$7.1X10^{4}$	$1.9X10^{6}$

[a] A_1 and/or A_2 values include contributions from daughter nuclides with half-lives less than 10 days.
[b] The values of A_1 and A_2 in Curies (Ci) are approximate and for information only; the regulatory standard units are terabecquerels (TBq).
[c] The quantity may be determined from a measurement of the rate of decay or a measurement of the radiation level at a prescribed distance from the source.
[d] These values apply only to compounds of uranium that take the chemical form of UF_6, UO_2F_2 and $UO_2(NO_3)_2$ in both normal and accident conditions of transport.
[e] These values apply only to compounds of uranium that take the chemical form of UO_3, UF_4, UCl_4 and hexavalent compounds in both normal and accident conditions of transport.
[f] These values apply to all compounds of uranium other than those specified in notes d and e of this table.
[g] These values apply to unirradiated uranium only.
[h] A_1 = 0.1 TBq (2.7 Ci) and A_2 = 0.001 TBq (0.027 Ci) for Cf-252 for domestic use.
[i] A_2 = 0.74 TBq (20 Ci) for Mo-99 for domestic use.

G. Table 2. Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides.

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)

Ac-225	Actinium (89)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ac-227		$1.0X10^{-1}$	$2.7X10^{-12}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ac-228		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-105	Silver (47)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-108m (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-110m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-111		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Al-26	Aluminum (13)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Am-241	Americium (95)	1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-242m (b)		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-243 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ar-37	Argon (18)	$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ar-39		$1.0X10^{7}$	$2.7X10^{-4}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ar-41		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
As-72	Arsenic (33)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
As-73		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
As-74		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
As-76		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
As-77		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
At-211	Astatine (85)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-193	Gold (79)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-194		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Au-195		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-198		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Au-199		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Ba-131	Barium (56)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-133		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-133m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-140 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Be-7	Beryllium (4)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Be-10		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-205	Bismuth (83)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-206		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bi-207		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-210		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-210m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bi-212 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bk-247	Berkelium (97)	1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Bk-249		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Br-76	Bromine (35)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Br-77		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Br-82		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
C-11	Carbon (6)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
C-14		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-41	Calcium (20)	$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-45		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-47		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-109	Cadmium (48)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-113m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-115		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-115m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$

Ce-139	Cerium (58)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-141		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ce-143		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-144 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cf-248	Californium (98)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-249		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cf-250		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-251		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cf-252		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-253		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cf-254		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cl-36	Chlorine (17)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cl-38		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-240	Curium (96)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-241		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cm-242		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-243		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-244		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-245		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cm-246		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cm-247		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-248		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Co-55	Cobalt (27)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-56		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Co-57		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-58		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

Co-58m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Co-60		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cr-51	Chromium (24)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Cs-129	Cesium (55)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-131		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cs-132		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-134		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cs-134m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-135		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Cs-136		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-137 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cu-64	Copper (29)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cu-67		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Dy-159	Dysprosium (66)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Dy-165		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Dy-166		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Er-169	Erbium (68)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Er-171		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-147	Europium (63)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-148		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-149		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Eu-150 (short lived)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-150 (long lived)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-152		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-152m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Eu-154		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-155		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Eu-156		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
F-18	Fluorine (9)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-52	Iron (26)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-55		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-59		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-60		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ga-67	Gallium (31)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ga-68		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ga-72		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Gd-146	Gadolinium (64)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Gd-148		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Gd-153		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Gd-159		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ge-68	Germanium (32)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ge-71		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ge-77		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Hf-172	Hafnium (72)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-175		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-181		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-182		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-194	Mercury (80)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-195m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-197		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Hg-197m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Hg-203		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ho-166	Holmium (67)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ho-166m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-123	Iodine (53)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
I-124		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-125		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-126		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-129		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-131		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-132		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-133		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-134		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-135		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-111	Indium (49)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-113m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-114m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-115m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ir-189	Iridium (77)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ir-190		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ir-192		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ir-194		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
K-40	Potassium (19)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
K-42		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
K-43		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Kr-81	Krypton (36)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Kr-85		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{4}$	$2.7X10^{-7}$

Kr-85m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{10}$	$2.7X10^{-1}$
Kr-87		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
La-137	Lanthanum (57)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
La-140		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Lu-172	Lutetium (71)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Lu-173		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-174		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-174m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-177		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Mg-28	Magnesium (12)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mn-52	Manganese (25)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mn-53		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{9}$	$2.7X10^{-2}$
Mn-54		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Mn-56		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mo-93	Molybdenum (42)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Mo-99		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
N-13	Nitrogen (7)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Na-22	Sodium (11)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Na-24		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Nb-93m	Niobium (41)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Nb-94		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nb-95		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nb-97		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nd-147	Neodymium (60)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Nd-149		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ni-59	Nickel (28)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ni-63		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ni-65		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Np-235	Neptunium (93)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Np-236 (short-lived)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Np-236 (long-lived)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Np-237 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Np-239		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-185	Osmium (76)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Os-191		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-191m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-193		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Os-194		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
P-32	Phosphorus (15)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
P-33		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pa-230	Protactinium (91)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pa-231		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Pa-233		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pb-201	Lead (82)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-202		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-203		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-205		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pb-210 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$

Pb-212 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pd-103	Palladium (46)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pd-107		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pd-109		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-143	Promethium (61)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-144		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-145		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pm-147		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pm-148m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-149		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-151		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Po-210	Polonium (84)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pr-142	Praseodymium (59)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pr-143		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-188	Platinum (78)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-191		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-193		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pt-193m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pt-195m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-197		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-197m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pu-236	Plutonium (94)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-237		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pu-238		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-239		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$

Pu-240		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Pu-241		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pu-242		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-244		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ra-223 (b)	Radium (88)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-224 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-225		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-226 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ra-228 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Rb-81	Rubidium (37)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-83		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-84		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-86		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Rb-87		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rb(nat)		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Re-184	Rhenium (75)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-184m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-186		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-187		$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Re-188		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Re-189		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re(nat)		$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Rh-99	Rhodium (45)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-101		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rh-102		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-102m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Rh-103m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Rh-105		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rn-222 (b)	Radon (86)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ru-97	Ruthenium (44)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ru-103		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ru-105		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ru-106 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
S-35	Sulphur (16)	$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Sb-122	Antimony (51)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sb-124		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sb-125		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sb-126		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sc-44	Scandium (21)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sc-46		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sc-47		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sc-48		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Se-75	Selenium (34)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Se-79		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Si-31	Silicon (14)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Si-32		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sm-145	Samarium (62)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sm-147		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sm-151		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Sm-153		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-113	Tin (50)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-117m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Sn-119m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-121m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-123		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-125		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sn-126		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-82	Strontium (38)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-85		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-85m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sr-87m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-89		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-90 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sr-91		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-92		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
T(H-3)	Tritium (1)	$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Ta-178 (long-lived)	Tantalum (73)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ta-179		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ta-182		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Tb-157	Terbium (65)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tb-158		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tb-160		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-95m	Technetium (43)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-96		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-96m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-97		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Tc-97m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-98		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

Tc-99		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-99m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-121	Tellurium (52)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-121m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Te-123m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-125m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-127		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-127m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-129		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-129m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-131m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-132		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Th-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-228 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-229 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Th-230		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-231		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Th-232		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-234 (b)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Th (nat) (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ti-44	Titanium (22)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Tl-200	Thallium (81)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-201		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-202		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-204		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{4}$	$2.7X10^{-7}$
Tm-167	Thulium (69)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Tm-170		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tm-171		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
U-230 (fast lung absorption) (b),(d)	Uranium (92)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-230 (medium lung absorption) (e)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-230 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-232 (fast lung absorption) (b),(d)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U-232 (medium lung absorption) (e)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-232 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-233 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-233 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-233 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-234 (fast lung		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$

absorption) (d)					
U-234 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-234 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-235 (all lung absorption types) (b),(d),(e),(f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-236 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-236 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-236 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-238 (all lung absorption types) (b),(d),(e),(f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U (nat) (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U (enriched to 20% or less) (g)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U (dep)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
V-48	Vanadium (23)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
V-49		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$

W-178	Tungsten (74)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
W-181		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-185		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-187		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
W-188		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Xe-122	Xenon (54)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Xe-123		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Xe-127		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Xe-131m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{4}$	$2.7X10^{-7}$
Xe-133		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{4}$	$2.7X10^{-7}$
Xe-135		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{10}$	$2.7X10^{-1}$
Y-87	Yttrium (39)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-88		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-90		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Y-91		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-91m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-92		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Y-93		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Yb-169	Ytterbium (70)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Yb-175		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Zn-65	Zinc (30)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zn-69		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zn-69m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-88	Zirconium (40)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-93 (b)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Zr-95		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

Zr-97 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

[a](Reserved)

[b]Parent nuclides and their progeny included in secular equilibrium are listed in the following:

Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Cs-137	Ba-137m
Ce-134	La-134
Ce-144	Pr-144
Ba-140	La-140
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Rn-220	Po-216
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208(0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-226	Ra-222, Rn-218, Po-214
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-nat	Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-234	Pa-234m
U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-nat	Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214,

	Po-214, Pb-210, Bi-210, Po-210
U-240	Np-240m
Np-237	Pa-233
Am-242m	Am-242
Am-243	Np-239

[c](Reserved)
[d]These values apply only to compounds of uranium that take the chemical form of UF_6, UO_2F_2 and $UO_2(NO_3)_2$ in both normal and accident conditions of transport.
[e]These values apply only to compounds of uranium that take the chemical form of UO_3, UF_4, UCl_4 and hexavalent compounds in both normal and accident conditions of transport.
[f]These values apply to all compounds of uranium other than those specified in notes (d) and (e) of this table.
[g]These values apply to unirradiated uranium only.

H. Table 3. General Values for A_1 and A_2.

Contents	A_1		A_2		Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limits for exempt consignments (Bq)	Activity limits for exempt consignments (Ci)
	(TBq)	**(Ci)**	**(TBq)**	**(Ci)**				
Only beta or gamma emitting radionuclides are known to be present	1×10^{-1}	2.7×10^{0}	2×10^{-2}	5.4×10^{-1}	1×10^{1}	2.7×10^{-10}	1×10^{4}	2.7×10^{-7}
Only alpha emitting radionuclides are known to be present	2×10^{-1}	5.4×10^{0}	9×10^{-5}	2.4×10^{-3}	1×10^{-1}	2.7×10^{-12}	1×10^{3}	2.7×10^{-8}
No relevant data are available	1×10^{-3}	2.7×10^{-2}	9×10^{-5}	2.4×10^{-3}	1×10^{-1}	2.7×10^{-12}	1×10^{3}	2.7×10^{-8}

I. Table 4. Activity-Mass Relationships for Uranium.

Uranium Enrichment[1] wt % U-235 present	Specific Activity	
	TBq/g	Ci/g
0.45	1.8×10^{-8}	5.0×10^{-7}
0.72	2.6×10^{-8}	7.1×10^{-7}

1	2.8×10^{-8}	7.6×10^{-7}
1.5	3.7×10^{-8}	1.0×10^{-6}
5	1.0×10^{-7}	2.7×10^{-6}
10	1.8×10^{-7}	4.8×10^{-6}
20	3.7×10^{-7}	1.0×10^{-5}
35	7.4×10^{-7}	2.0×10^{-5}
50	9.3×10^{-7}	2.5×10^{-5}
90	2.2×10^{-6}	5.8×10^{-5}
93	2.6×10^{-6}	7.0×10^{-5}
95	3.4×10^{-6}	9.1×10^{-5}
[1]The figures for uranium include representative values for the activity of the uranium-234 that is concentrated during the enrichment process.		

12VAC5-481-3780. Nationally Tracked Source Thresholds.

The terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16
Americium-241/Be	60	1,600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14
Cesium-137	100	2,700	1	27
Gadolinium-	1,000	27,000	10	270

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Iridium-192	80	2,200	0.8	22
Plutonium-238	60	1,600	0.6	16
Plutonium-239/Be	60	1,600	0.6	16
Polonium-210	60	1,600	0.6	16
Promethium-147	40,000	1,100,000	400	11,000
Radium-226	40	1,100	0.4	11
Selenium-75	200	5,400	2	54
Strontium-90	1,000	27,000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81

Forms (12VAC5-481)

Applications for a New Radioactive Material License

- Academic, Research and Development, and Other Licenses of Limited Scope, Revision 3 (1/2016)
- Broad Scope, Revision 3 (1/2016)
- Fixed Gauge Devices, Revision 3 (1/2016)
- Industrial Radiography, Revision 3 (1/2016)
- Irradiators - Part XII, Revision 1 (1/2016)
- Medical Use, Revision 2 (1/2016)
- Portable Gauges, Revision 2 (1/2016)
- Radiopharmacy, Revision 1 (1/2016)

- Sealed Sources, Revision 3 (1/2016)
- Self-Shielded Irradiators, Revision 3 (1/2016)
- Material in Well Logging, Tracer, and Field Flood Study, Revision 3 (1/2016)
- XRF Devices, Revision 2 (1/2016)

Applications for Renewal of a Radioactive Material License

- Academic, Research and Development and Other Licenses of Limited Scope, Revision 3 (1/2016)
- Broad Scope, Revision 3 (1/2016)
- Fixed Gauge Devices, Revision 3 (1/2016)
- Industrial Radiography, Revision 3 (1/2016)
- Irradiators - Part XII, Revision 0 (7/2016)
- Medical Use, Revision 2 (1/2016)
- Portable Gauges, Revision 4 (1/2016)
- Radiopharmacy, Revision 1 (1/2016)
- Sealed Sources, Revision 3 (1/2016)
- Self-Shielded Irradiators, Revision 3 (1/2016)
- Material in Well Logging, Tracer, and Field Flood Study, Revision 3 (1/2016)
- XRF Devices, Revision 4 (1/2016)

Training, Experience, and Preceptor Attestations

- A: Radiation Safety Officer for Medical Use, Revision 0 (7/2016)
- B: Authorized User - Written Directive Not Required, Revision 0 (7/2016)
- C: Unsealed Radioactive Material Requiring Written Directive, Revision 2, (6/2014)
- D: Authorized User for Manual Brachytherapy Sources, Revision 0 (7/2016)
- E: Authorized User of Remote Afterloader, Teletherapy, or Gamma Stereotactic Radiosurgery Units, Revision 0 (7/2016)
- F: Authorized Medical Physicist, Revision 0 (7/2016)
- G: Authorized Nuclear Pharmacist, Revision 0 (7/2016)

Other Forms

- Certificate of Disposition of Materials, Revision 0 (7/2016)
- Certificate - Use of Depleted Uranium under General License, Revision 0 (7/2016)

Cumulative Occupational Exposure History, Revision 1 (1/2015)

Fingerprint Record, Federal Bureau of Investigation, FD-258, (rev. 9/2013)

Notice to Employees, RH-F-12 (1/2011)

Occupational Exposure Record per Monitoring Period, Revision 1 (1/2015)

Registration Certificate - In Vitro Testing with Radioactive Material under General License, Revision 0 (7/2016)

Reciprocity Privileges Checklist, Revision 0 (7/2016)

Documents Incorporated by Reference (12VAC5-481)

Dosimetry of X-ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV: NCRP Report 69, 1981, National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Washington, DC 20014

Comprehensive QA for Radiation Oncology: AAPM Report No. 46, 1994, American Association of Physicists in Medicine, Committee Task Group 40, Radiation Therapy Committee, published by the American Institute of Physics, One Physics Ellipse, College Park, MD 20740-3846

AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report Number 47, 1994, American Association of Physicists in Medicine Radiation Therapy Task Group 45, published by the American Institute of Physics, One Physics Ellipse, College Park, MD 20740-3846

Guidance document on delivery, treatment planning, and clinical implementation of IMRT: Report of the IMRT subcommittee of the AAPM radiation therapy committee: AAPM Report No. 82, Medical Physics, Vol. 30, No. 8, August 2003, American Association of Physicists in Medicine

Quality assurance for computed tomography simulators and the computed tomography-simulation process: Report of the AAPM Radiation Therapy Committee Task Group No. 66: AAPM Report No. 83, Medical Physics, Vol. 30, No. 10, October 2003, American Association of Physicists in Medicine