Commonwealth of Virginia
Radiation Protection Regulatory Guide

Guidance for Manufacturing and Distribution Licenses

ORH-720 L

Virginia Department of Health
Radioactive Materials Program
109 Governor Street, Room 730
Richmond, VA 23219

EXECUTIVE SUMMARY

Virginia Regulatory Guides (**VAREGS**) are issued to describe and make available to the applicant or licensee, acceptable methods of implementing specific parts of **12VAC5- 481, 'Virginia Radiation Protection Regulations',** to delineate techniques used by the staff in evaluating past specific problems or postulated accidents, and to provide guidance to applicants or licensees. VAREGS are not substitutes for **12VAC5-481, 'Virginia Radiation Protection Regulations'**, therefore compliance with them is not required. Methods and solutions different from those set forth in this guide will be acceptable if they provide a basis for the Virginia Department of Health (VDH), Radioactive Materials Program to determine if a radiation protection program meets the current rule and protects health and safety.

Comments and suggestions for improvements in this VAREG are encouraged and it will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Comments should be sent to: **Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219.**

Requests for single copies of this guide (which may be reproduced) can be made in writing to: Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219. This guide is also available on our website: http://www.vdh.virginia.gov/Epidemiology/RadiologicalHealth/.

This VAREG, 'Guidance for Manufacturing and Distribution Licenses' has been developed to streamline the application process for a Manufacturing and Distribution license. A copy of the application VDH form, 'Application for a Radioactive Material License Authorizing Manufacturing and Distribution' is located in **Appendix A** of this guide.

Appendixes C through **Q** provide examples, models and additional information that can be used when completing the application.

It typically takes 60-90 days for a license to be processed and issued if the application is complete. When submitting the application be sure to include the appropriate application fee listed in **12VAC5-490**.

In summary, the applicant will need to do the following to submit an application for a Manufacturing and Distribution license:

- Use this regulatory guide to prepare the application, VDH form, 'Application for a Radioactive Material License Authorizing Manufacturing and Distribution' (**Appendix A**).
- Complete the application, VDH form, 'Application for a Radioactive Material License Authorizing Manufacturing and Distribution' (**Appendix A**). See 'Contents of Application' of the guide for additional information.
- Include any additional attachments.

  All supplemental pages should be on 8 ½" x 11" paper.

  Please identify all attachments with the applicant's name and license number (if a renewal).
- Avoid submitting proprietary information unless it is absolutely necessary. If submitted, proprietary information and other sensitive information should be clearly identified and a request made to withhold from public disclosure.
- Submit an original signed application along with attachments (if any). This submission can be made via scanned copies forwarded via facsimile or electronic mail or via postal mail of the documents.
- Submit the application fee (for new licensees only).
- Retain one copy of the licensee application and attachments (if any) for your future reference. You will need this information because the license will require that radioactive material be possessed and used in accordance with statements, representation, and procedures provided in the application and supporting documentation.

If you have any questions about the application process, please contact this office at (804) 864-8150.

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ABBREVIATIONS

ALARA	As low as reasonably achievable
ALI	annual limit on intake
AU	Authorized User
bkg	Background
Bq	Becquerel
cc	centimeter cubed
CDE	Committed Dose Equivalent
CEDE	Committed Effective Dose Equivalent
Ci	Curie
CFR	Code of Federal Regulations
cc	centimeter cubed
cm^2	centimeter squared
cpm	counts per minute
C/kg	Coulombs/Kilogram
cpm	Counts Per Minute
DFP	Decommissioning Funding Plan
DIS	Decay-In-Storage
DOE	United States Department of Energy
DOT	United States Department of Transportation
dpm	Disintegrations Per Minute
EDE	Effective Dose Equivalent
EPA	United States Environmental Protection Agency
F/A	Financial Assurance
FDA	United States Food and Drug Administration
FR	Federal Register
GM	Geiger-Mueller
GBq	Gigabecquerel
IN	Information Notice
LLW	Low Level Waste
GPO	Government Printing Office
IN	Information Notice
MBq	Megabecquerel
mCi	millicurie
mGy	Milligray
mR	Milliroentgen
mrem	millirem
mSv	millisievert
NIST	National Institute of Standards and Technology
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OSL	Optical Stimulated Luminescent Dosimeters
R	Roentgen
RG	Regulatory Guide
RQ	Reportable Quantities
RSO	Radiation Safety Officer
SDE	Shallow Dose Equivalent

SI	International System of Units (abbreviated SI from the French Le Systeme Internationale d'Unites)
SS&D	Sealed Source and Devices Bulletin Board System (BBS)
SSDR	Sealed Source and Device Registration
Sv	Sievert
T1/2	Half-life
TEDE	Total effective dose equivalent
TI	Transportation Index
TLD	Thermoluminescent dosimeters
VDH	Virginia Department of Health
μCi	microcurie
%	percent

PURPOSE OF GUIDE

This document discusses three types of licenses associated with the manufacturing and distribution of radioactive materials and products containing radioactive materials. It provides guidance to an applicant in preparing a license application for one of these license types: manufacturing and distribution; distributing only and distributing (only) for medical use, as well as agency criteria for evaluating the license application.

The body of this document contains the standard requirements and guidance for the first two types of licenses: (1) manufacturing, including distribution of products to other specific licensees authorized to receive the products; and (2) distribution only (which requires a separate distribution license). **Appendix Q** of this document contains the standard requirements and guidance for the third type of materials licenses for the distribution (only) and transfer of radioactive drugs, sealed sources, and devices directly to medical use licensees. Note that this guidance does not apply to special nuclear material.

For the purpose of this VAREG, materials manufacturers are those licensees that process raw material and/or sources and distribute those processed materials or manufactured products to users as finished products. Examples are: major radiopharmaceutical processor/manufacturers (not radiopharmacies); sealed source fabricators; device manufacturers; and other manufacturing licensees that possess and use irradiated bulk quantities of raw materials or sources.

As noted above, this guide also applies to licensing for distribution to specific licensees and to medical use licensees.

Quality control for finished products is part of the manufacturer licensee's responsibilities. These obligations are described in the regulations of **12VAC5-481 'Virginia Radiation Protection Regulations', Part III 'Licensing of Radioactive Material'**. Quality control of finished products to be distributed to general licensees or individuals exempt from licenses are listed in NRC's NUREG-1556, Vol. 16 and Vol 8, respectively.

This guide identifies information needed to complete VDH form, 'Application for a Radioactive Material License Authorizing Manufacturing and Distribution' (**Appendix A**) for possession and use of byproduct,

source and/or special nuclear materials for manufacturing and distribution. If a license of broad scope is being sought, also refer to VAREG ORH-720 H, 'Guidance for Broad Scope Licensees'.

The format within this document for each item of technical information is as follows:

- **Rule**--references the requirements from **12VAC5-481 'Virginia Radiation Protection Regulations'** applicable to the item;
- **Criteria**--outlines the criteria used to judge the adequacy of the applicant's response;
- **Discussion**--provides additional information on the topic sufficient to meet the needs of most readers.

The information submitted in the application must be sufficient to demonstrate that proposed equipment, facilities, personnel, and procedures are adequate to protect the health and safety of the citizens of Commonwealth of Virginia according with the agency's guidelines. Submission of incomplete or inadequate information will result in delays in the approval process for the license. Additional information will be requested when necessary to ensure that an adequate radiation safety program has been established. Such requests for additional information will delay completion of the application's review and may be avoided by a thorough study of the rule(s) and these instructions prior to submitting the application.

12VAC5-481 'Virginia Radiation Protection Regulations' requires the applicant and/or licensee to develop, document, and implement procedures that will ensure compliance with the rule. The appendices describe radiation protection procedures. Each applicant should read the rule and procedures carefully and then decide if the procedure addresses specific radiation protection program needs at the applicant's facility. Applicants may adopt a procedure included in this VAREG or they may develop their own procedures to comply with the applicable rule.

In this guide, "dose" or "radiation dose" means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent (TEDE). These terms are defined in the **12VAC5-481-10.** Rem and Sievert (Sv), its SI equivalent (1 rem = 0.01 Sv), are used to describe units of radiation exposure or dose. These units are used because **12VAC5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation',** sets dose limits in terms of rem, not rad or roentgen. Furthermore, radioactive materials commonly used in medicine emit beta and photon radiation, for which the quality factor is 1; a

useful rule of thumb is an exposure of 1 roentgen is equivalent to an absorbed dose of 1 rad and dose equivalent of 1 rem.

This VAREG provides the latest guidance, shows the requirements in terms of the **12VAC5-481, 'Virginia Radiation Protection Regulations',** and provides a user-friendly format to assist with the preparation of a license application.

LICENSES

Applicants should study this document, related guidance, and all applicable regulations carefully before completing the VDH form ‘Application for a Radioactive Material License Authorizing Manufacturing and Distribution’. VDH expects licensees to provide requested information on specific aspects of their proposed radiation protection program in attachments to the application. When necessary, VDH may ask the applicant for additional information to gain reasonable assurance that an adequate radiation protection program has been established.

After a license is issued, the licensee must conduct its program in accordance with the following:

- Statements, representations, and procedures contained in the application and in correspondence with VDH;
- Terms and conditions of the license; and
- **12VAC5-481 ‘Virginia Radiation Protection Regulations’**.

THE 'AS LOW AS IS REASONABLY ACHIEVABLE (ALARA)' CONCEPT

12VAC5-481-630, Radiation protection programs, states that *"each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities"* and *"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...ALARA."* This section also requires that licensees review the content of the radiation protection program and its implementation annually.

Information directly related to radiation protection standards in **12VAC5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation'**, is contained in:

- NRC's NUREG-1736, 'Consolidated Guidance: 10 CFR Part 20 - Standards for Protection Against Radiation.'

Applicants should consider the ALARA philosophy detailed in these reports when developing plans to work with licensed radioactive materials.

WHO REGULATES AT FACILITIES IN THE COMMONWEALTH OF VIRGINIA?

In the special situation of work at federally controlled sites in Commonwealth of Virginia, it is necessary to know the jurisdictional status of the land to determine whether Nuclear Regulatory Commission (NRC) or VDH has regulatory authority. NRC has regulatory authority over land determined to be under "exclusive federal jurisdiction," while VDH has jurisdiction over non-exclusive federal jurisdiction land (see **Table 1**). Applicants and licensees are responsible for finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. VDH recommends that applicants and licensees ask their local contacts for the federal agency controlling the site (e.g., contract officer, base environmental health officer, district office staff) to help determine the jurisdictional status of the land and to provide the information in writing, so that licensees can comply with NRC or VDH regulatory requirements, as appropriate. The following table lists examples of regulatory authority.

Table 1. Who Regulates the Activity?

Applicant and Proposed Location of Work	Regulatory Agency
Federal agency regardless of location (except that Department of Energy [DOE] and, under most circumstances, its prime contractors are exempt from licensing [**10 CFR 30.12**])	NRC
Non-federal entity in non-Agreement State, U.S. territory, or possession	NRC
Non-federal entity in Virginia at non-federally controlled site	VDH
Non-federal entity in Virginia at federally-controlled site not subject to exclusive federal jurisdiction	VDH
Non-federal entity in Virginia at federally-controlled site subject to exclusive federal jurisdiction	NRC

A current list of Agreement States (States that have entered into agreements with the NRC that give them the authority to license and inspect radioactive material used or possessed within their borders), including names, addresses, and telephone numbers of responsible officials are maintained by the NRC Office of Federal and State Materials and Environmental Management Programs and is available on their website: http://nrc-stp.ornl.gov/.

MANAGEMENT RESPONSIBILITY

VDH endorses the philosophy that effective radiation protection program management is vital to safe operations that comply with VDH regulatory requirements.

"Management" refers to the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities or that person's delegate or delegates.

To ensure adequate management involvement, a management representative (i.e., chief executive officer or delegate) must sign the submitted application acknowledging management's commitments to and responsibility for the following:

- Radiation protection, security and control of radioactive materials, and compliance with rule;
- Knowledge about the contents of the license application;
- Compliance with current VDH and United States Department of Transportation (DOT) regulations and the licensee's operating and emergency procedures;
- Provision of adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that the public, and workers are protected from radiation hazards;
- Appointment of a qualified individual who has agreed in writing to work as RSO;

Management may delegate individuals (i.e., an RSO or other designated individual) to submit amendment requests to VDH. A correspondence delegation letter must be completed, signed by management, and submitted to VDH. A sample letter has been included in **Appendix D.**

SAFETY CULTURE

Nuclear safety culture is defined as the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment. Individuals and organizations performing regulated activities bear the primary responsibility for safely handling and securing these materials. Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal conflict situations (e.g., production versus safety, schedule versus safety, and cost of the effort versus safety). **Table 2** show traits of a positive nuclear safety culture.

Table 2: Traits of a Positive Nuclear Safety Culture

Trait	Result
Leadership: Safety Values and Actions	Leaders demonstrate a commitment to safety in their decisions and behaviors
Problem Identification and Resolution	Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance
Personal Accountability	All individuals take personal responsibility for safety
Evaluating Work Processes	The process of planning and controlling work activities is implemented so that safety is maintained
Continuous Learning	Opportunities to learn about ways to ensure safety are sought out and implemented
Environment for Raising Concerns	A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination
Effective Safety Communications	Communications maintain a focus on safety
Respectful Work Environment	Trust and respect permeate the organization
Questioning Attitude	Individuals avoid complacency and continually challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action

Individuals and organizations performing regulated activities are expected to establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This applies to all licensees, holders of quality assurance programs approvals, vendors, and suppliers of safety-related components, and applicants for a license or quality assurance program approval, subject to VDH authority. More information relating to safety culture can be found at: http://www.nrc./about-nrc/regulatory/enforcement/safety-culture.html

APPLICABLE RULE

It is the applicant's or licensee's responsibility to obtain, read, and follow **12VAC5-481, 'Virginia Radiation Protection Regulations'**.

The following parts of **12VAC5-481, 'Virginia Radiation Protection Regulations'** contain requirements applicable to manufacturing and distribution licensees:

- Part I: 'General Provisions'
- Part III: 'Licensing of Radioactive Materials;
- Part IV: 'Standards for Protection Against Radiation'
- Part X: 'Notices, Instructions and Reports to Workers'
- Part XIII: 'Transportation of Radioactive Material'

Requests for single copies of the above documents (which may be reproduced) can be made in writing to: **Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219** or for an electronic copy go to our web site at: http://www.vdh.virginia.gov/Epidemiology/RadiologicalHealth/.

HOW TO FILE

Applicants for a materials license should do the following:

- Be sure to use the current guidance from VDH in preparing an application.
- Complete VDH form, 'Application for Radioactive Material License Authorizing Manufacturing and Distribution.' (**Appendix A**).
- For each separate sheet, other than submitted with the application, identify and key it to the item number on the application, or the topic to which it refers.
- Submit all documents on 8 ½ x 11 inch paper.
- Avoid submitting proprietary information unless it is absolutely necessary. If submitted, proprietary information and other sensitive information should be clearly identified and a request made to withhold from public disclosure.
- Submit an original, signed application. This submission can be made using scanned copies forwarded via facsimile or electronic mail or via postal mail of the documents.
- Retain one copy of the license application for your future reference.

Deviations from the suggested wording of responses as shown in this VAREG or submission of alternative procedures will require a more detailed review.

Note: Personal employee information (i.e., home address, home telephone number, Social Security Number, date of birth, and radiation dose information) should not be submitted unless specifically requested by VDH**.**

WHERE TO FILE

Applicants wishing to possess or use radioactive material in Commonwealth of Virginia are subject to the requirements of **12VAC5-481, 'Virginia Radiation Protection Regulations'** and must file a license application with:

Virginia Department of Health
Radioactive Materials Program
109 Governor Street, Room 730
Richmond, VA 23219

LICENSE FEES

The appropriate fee must accompany each application or license amendment request. Refer to **12VAC5-490** to determine the amount of the fee. VDH will not issue the new license prior to fee receipt. Once technical review has begun, no fees will be refunded. Application fees will be charged regardless of VDH's disposition of an application or the withdrawal of an application.

Licensees are also subject to annual fees; refer to **12VAC5-490**.

Direct all questions about VDH's fees or completion of **Item 10** of VDH form, 'Application for a Radioactive Material License Authorizing Manufacturing and Distribution' **(Appendix A)** to: Virginia Department of Health,, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219 or call (804) 864-8150.

CONTENTS OF AN APPLICATION

Item 1: Type of Application

Obtain the correct application form for either a new license or a renewal, check the appropriate box and, if applicable, list the license number for a renewal.

This guide is written to instruct a new licensee in the process of applying for a radioactive material license. Not all discussions will be appropriate to a licensee renewing an existing license.

Item 2: Name and Mailing Address of Applicant

List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent. A Post Office box number is an acceptable mailing address.

Notify the agency of changes in the mailing address.

The licensee must also provide sufficient information for the agency to ensure the proposed corporation or controlling legal entity is a valid entity. Verification of this identity can be accomplished by submitting a copy of the company's license from the NRC or another Agreement State or a government contract or certification, etc.

Note: The agency must be notified in the event of change of ownership or control and bankruptcy proceedings; see below for more details.

Timely Notification of Transfer of Control

Rule: 12VAC5-481-330, 12VAC5-481-450, 12VAC5-481-500

Criteria: Licensees must provide full information and obtain VDH's **written consent prior** to transferring ownership or control of the license, or, as some licensees call it, 'transferring the license'.

Discussion: Transfer of control may be the results of mergers, buyouts, or majority stock transfers. Although it is not VDH's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain prior VDH written consent. This is to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid licenses issued by VDH;
- Materials are properly handled and secured;
- Persons using these materials are competent and committed to implementing appropriate radiological controls;
- A clear chain of custody is established to identify who is responsible for final disposal of the possessed material; and
- Public health and safety are not compromised by the use of such materials.

Appendix C identifies the information to be provided about changes of ownership or transfer of control.

Notification of Bankruptcy Proceedings

Rule: 12VAC5-481-500

Criteria: 12VAC5-481-500 states: "*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*" and "*…shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of filing of the petition*".

Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains responsible for all regulatory requirements. VDH needs to know when licensees are in bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled, and whether there are any public health and safety concerns (e.g.; contaminated facility). VDH shares the results of its determinations with other involved entities (e.g.; trustees), so that health and safety issues can be resolved prior to completion of bankruptcy proceedings.

Licensees must notify VDH immediately of the filing of a bankruptcy petition.

Item 3: Person to Be Contacted Regarding Application

Criteria: Identify the individual who can answer questions about the application and include his or her telephone number.

Discussion: This is typically the proposed Radiation Safety Officer (RSO), unless the applicant has named a different person as the contact. The agency will contact this individual if there are questions about the application.

Notify the agency if the contact person or his or her telephone number changes so that the agency can contact the applicant or licensee in the future with questions, concerns, or information. This notice is 'for information only' and does not require a license amendment.

Item 4: Address(es) Where Radioactive Material Will Be Used or Possessed

Rule: 12VAC5-481-450, 12VAC5-481-500

Criteria: Applicants must provide a specific address for each location where radioactive material will be used, stored, or dispatched.

Discussion: Specify the street address, city, and state or other descriptive address (e.g., on Highway 58, 5 miles east of the intersection of Highway 11E and State Route 16, Anytown, VA) for each facility at which licensed material will be used or stored. The descriptive address should be sufficient to allow a VDH inspector to find the use/storage location. **A Post Office Box address is not acceptable**. In addition, state whether the sealed sources will be used at temporary jobsites.

Applicants should identify all facilities, designed or established for specials uses, e.g., interim or long-term waste storage facilities, high activity laboratories, etc. A VDH-approved license amendment identifying a new location of possession or possession and use, which is not encompassed by a location

described on the existing license, is required before receiving, using, and storing licensed material at that location.

Being granted a VDH license does not relieve a licensee from complying with other applicable federal, state, or local regulations (e.g., local zoning requirements for storage locations).

Documents that give the exact location of use and storage for materials greater than or equal to International Atomic Energy Agency (IAEA) Category 2 quantities should be marked as sensitive information, not for public consumption.

Note*:* As discussed later under "*Financial Assurance and Record keeping for Decommissioning*", licensees need to maintain permanent records on where licensed material was used or stored while the license was in force. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). Acceptable records are sketches or written descriptions of storage or use locations specifically listed on the license. Licensees do not need to maintain this information for temporary job sites or temporary storage locations where sources have never leaked.

Radiation Safety Officer and Authorized Users

Item 5: Individual(s) Responsible for Radiation Safety Program and Their Training and Experience

Rule: **12VAC5-481-450, 12VAC5-481-2270**

Criteria: Executive management, the Radiation Safety Officer (RSO), and users work as a team to implement the radiation protection program. Each individual and position plays a critical role within his/her area of responsibility. The roles and responsibilities of executive management, the RSO, the Radiation Safety Office staff, users, and others in restricted areas are discussed in the sections that follow. Refer to subsequent section specific to the RSO and Authorized Users described above.

Note: NRC's NUREG-1556, "Management of Radioactive Material Safety Programs at Medical Facilities," describes the role of executive management and the RSO at medical facilities, but contains information that may be of help to the possession of manufacturing and distribution license.

Discussion: You must be qualified by training and experience to possess and use the material for the purpose requested in a manner that will protect health and minimize danger to life or property before an application for a license is approved.

Each program in which radioactive materials are possessed and used under a VDH license will have someone responsible for radiation safety and compliance with VDH's regulations. In a small program, the responsibility may be combined with or assigned to (or assumed by) the same individual using radioactive materials, therefore an authorized user may serve as an RSO. In a medium-size program, the responsibility may be assigned to an individual on a part-time basis, with that person's primary responsibility being in another area of work. In a large program, the many facets of occupational and environmental radiation safety require that responsibility for the radiation safety program be assigned to a qualified individual on a full-time basis. His or her training and experience must be commensurate with his or her duties and responsibilities. Supporting staff should be provided, as appropriate, for the size and scope of the program. A large program may have some or all of the following characteristics:

- In-house calibration of radiation survey, monitoring, and measurement instruments;

- The possession and use of multiple chemical and physical forms of multiple radionuclides for various purposes;
- Program flexibility with regard to the possession and use of radionuclides, their chemical and physical form, and the uses to be made of such radionuclides;
- The need for accurate detection, identification, and measurement of radioactivity in various types of effluents containing varying amounts of different radionuclides and for evaluation of these effluents against VDH regulatory requirements and limitations;
- The need for radioactive effluent treatment by filtration, absorption, adsorption, holdup, etc;
- The need for selection, evaluation, design, fabrication, maintenance, and use of radioactive effluent treatment systems;
- The need for the selection, evaluation, and maintenance of radiation measurement and analysis equipment;
- A potential for the contamination of facilities, equipment, and personnel accompanied by the need to control such contamination (including airborne contamination), decontaminate personnel and equipment, and evaluate possible internal dose (including determination of the need for bioassays and interpretation of bioassay results).

VDH holds the licensee responsible for the radiation protection program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted safely. Management responsibility and liability are sometimes underemphasized or not addressed in applications and are often poorly understood by licensee employees and managers. As discussed later in this guide, senior management will delegate to the RSO sufficient authority, organization freedom, and management prerogative to communicate with and direct personnel regarding VDH regulations and license provisions and to terminate unsafe activities involving licensed material. Other responsibilities will be delegated to other individuals. Such delegations should be clearly communicated to all parties. While these delegations are important to the operation of the program, the licensee senior management maintains the ultimate responsibility for the safety of licensed activities.

If a license of broad scope is being sought, also refer to VAREG ORH-720 H, ‘Guidance for Broad Scope Licensees’.

Item 5.1: Radiation Safety Officer (RSO)

Rule: 12VAC5-481-450 A, 12VAC5-481-490 B, 12VAC5-481-2270

Criteria: RSO must have adequate training and experience. The RSO is responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

Discussion: The person responsible for the radiation protection program is called the RSO. The RSO needs independent authority to stop operations that he or she considers unsafe. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. Typical RSO duties are described in **Appendix D**. VDH requires the name of the RSO on the license to ensure that licensee management has identified a qualified person and that the named individual knows of his or her designation as RSO.

VDH believes that to demonstrate adequate training and experience, the RSO should have: (1) at a minimum, a college degree at the bachelor level or equivalent training and experience in physical, chemical, biological sciences, or engineering, and (2) training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- Radiation Protection Principles
- Characteristics of Ionizing Radiation
- Units of Radiation Dose and Quantities
- Radiation Detection Instrumentation
- Biological Hazards of Exposure to Radiation (appropriate to the types and forms of licensed material to be possessed and used)
- **12VAC5-481**, 'Virginia Radiation Protection Regulations' and other appropriate regulations including DOT.
- Hands on Use of Radioactive Materials.

The amount of training and experience will depend on the type, form, quantity, and proposed use of the licensed material requested. For instance, in addition to a college degree, RSOs at a manufacturing company where workers handle curie quantities of radioactive material should be specialists in the field of radiation protection and may need 40 hours of radiation safety training specific to their job duties as well as a year of experience with similar types, forms, quantities, and uses of radioactive material before the individual is qualified to be RSO. On the other hand, RSOs at "manufacturers" who are importers of timepieces containing tritium that are received in the U. S. as completed products and distributed as exempt quantities may only require a few hours of radiation safety training and no prior experience with timepieces to be qualified as an RSO.

The proposed RSO's training and experience must be sufficient to identify and control the anticipated radiation hazards. The RSO should have experience planning and conducting evaluations, surveys, and measurements similar to those required by the radiation safety protection program. In addition, the RSO designee should have obtained the above training in a formal course designed for RSOs, presented by an academic institution, commercial radiation safety consulting company, or a professional organization of radiation protection experts.

Note: It is important to notify the agency, as soon as possible, of changes in the designation of the RSO**.**

Item 6: Authorized Users

Rule: 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-630, 12VAC5-481-2260, 12VAC5-481-2270, 12VAC5-481-2980

Criteria: Authorized users (AUs) must have adequate training and experience with the types and quantities of licensed material that they propose to possess and use.

Discussion: Applicants must name at least one individual who is qualified to use the requested licensed materials. An AU is a person whose training and experience meet VDH's criteria. This individual is named on the license and uses or directly supervises the use of licensed material. An AU is considered to be supervising the use of licensed material when he or she directs personnel in operations involving the material. The AU's primary responsibility is to ensure that radioactive materials are used safely and according to regulatory requirements. The AU is also responsible for ensuring that procedures and engineering controls are used to keep occupational doses and doses to members of the public ALARA. Although the AU may delegate specific tasks to supervised users (e.g., maintaining records), he or she is still responsible for safe use of licensed material.

AUs must have adequate and appropriate training to provide reasonable assurance that they will use licensed material safely, including maintaining security of, and access to, licensed material, and respond appropriately to events or accidents involving licensed material to prevent the spread of contamination.

The agency believes that to demonstrate adequate training and experience, the AU should have: (1) a college degree at the bachelor level, or equivalent training and experience in physical, chemical, or biological sciences or in engineering; and (2) training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- Radiation protection principles
- Characteristics of ionizing radiation
- Units of radiation dose and quantities
- Radiation detection instrumentation
- Biological hazards of exposure to radiation (appropriate to the types and forms of radioactive material to be used)
- Hands on use of radioactive material

The amount of training and experience needed will depend upon the type, form, quantity, and proposed use of the licensed material requested, but it should cover the subjects stated. For instance, in addition to a college degree, authorized users at a manufacturing company where workers handle curie quantities of radioactive material should have 40 hours of radiation safety training and a minimum of 6 months of experience with similar types, forms, quantities, and uses of radioactive material before the individual is qualified to be an authorized user. On the other hand, authorized users at "manufacturers" who are importers of timepieces containing tritium that are received in the U. S. as completed products and distributed as exempt quantities may only require a few hours of radiation safety training and no prior experience with timepieces. In general, AUs must demonstrate training and experience with the type and quantity of material that they propose to use. For example, someone with training and experience only with sealed radioactive sources may not be qualified to use or supervise the use of unsealed licensed material. In addition, someone with experience using only trace quantities may not understand the risks of working with much larger quantities of the same substance. Applicants should pay particular attention to the type of radiation involved. For example, someone experienced with gamma emitters may not have appropriate experience for high energy beta emitters.

An AU is considered to be supervising the use of radioactive materials when he/she directs personnel in operations involving the licensed material. Although the AU may delegate specific tasks to the supervised users (e.g., conducting surveys, keeping records), he/she is responsible for the safe use of radioactive material to assure that areas are not contaminated.

Note: Applicants for broad scope programs should refer to VAREG ORH-720 H, 'Guidance for Broad Scope Licensees'. Broad Scope programs may be permitted to name authorized users without amending the license.

Item 7: Training for Individuals Working In or Frequenting Restricted Areas

Rule: 12VAC5-481-30, 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-840, 12VAC5-481-2260, 12VAC5-481-2270, 12VAC5-481-2280

Criteria: Individuals whose assigned duties involve exposure to radiation and/or radioactive material (from both licensed and unlicensed sources), and in the course of their employment are likely to receive in a year an occupational dose of radiation greater than 1 mSv (100 mrem), whether from all external sources, all internal sources, or any combination, must receive instruction commensurate with their duties and responsibilities, as required by **12VAC5-481-2270**.

Discussion: Before beginning work with licensed material, individuals must receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program.

Each individual should also receive periodic refresher training at no more than 12-month intervals. Training should also be performed whenever there is a significant change in hazards, duties, procedures, regulations, or terms of the license.

Licensees should not assume that safety instruction has been adequately covered by prior employment or academic training. Site-specific training should be provided for all individuals. Ancillary personnel (e.g., clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and the appropriate precautions. The licensee should assess each individual's involvement with licensed material and cover each applicable subject appropriately.

Training may be in the form of lecture, demonstrations, videotape, or self-study, and it should emphasize practical subjects important to the safe possession and use of licensed material. If training is not conducted by an instructor, a method should be adopted whereby a trainee can ask questions and discuss topics relating to occupational radiation exposure. The guidance in **Appendix E**, Radiation Safety Training Topics, may be used to develop a training program. The program should consider all topics pertinent for each group of workers as well as the method and frequency of training. The licensee should determine whether the training succeeded in conveying the desired information and adjust the training program as necessary. This assessment may be performed by a written test or observation of the individual in the performance of assigned duties. Remedial training for missed test questions or other areas or apparent weakness should be conducted or additional formal training planned to cover deficient areas.

The person conducting the training should be a qualified individual (e.g., a person who meets the qualifications for RSO or authorized user on the license and is familiar with the licensee's program).

Radioactive Material

Item 8: Radioactive Material

Rule: 12VAC5-481-90, 12VAC5-481-150, 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-451, 12VAC5-481-510, 12VAC5-481-520, 12VAC5-481-530, 12VAC5-481-1161, 12VAC5-481, Part III,

Criteria: A specific license is required, describing and authorizing the manufacture or distribution of materials and devices to persons generally licensed, specifically licensed, or specifically licensed to distribute materials and devices to medical use licensees. Licenses authorized for distribution only to specifically licensed or generally licensed persons do not generally allow possession and processing of licensed materials. Licenses authorizing the distribution of materials to persons exempt from licensing are not described in this document. See NRC's NUREG-1556, Vol. 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses." If a license of broad scope is being sought, also refer to VAREG ORH-720 H, 'Guidance for Broad Scope Licensees'.

Discussion: Licensees are required to have a specific license authorizing manufacturing or incorporating licensed materials into devices or materials. Licensees or applicants desiring to incorporate a material into a sealed source or incorporate a sealed source into a device shall have the combination approved by the NRC or another agreement state, and listed in the Sealed Source & Device (SSD) Registry.

Licensees who possess and use licensed materials to support the process of manufacturing and/or distribution shall have the appropriate possession and uses described in their licensees. An example may

be that a manufacturer of depleted uranium counterweights or shields possesses and uses a cesium-137 level gauge to detect blockage in the raw material hopper feed line. The manufacturer would need authorization not only to possess, use, and distribute the uranium for the counterweights and the shields, but also authorization to possess and use the level gauging device. If the licensee wishes to calibrate its own survey meters and perform leakage/contamination tests, then separate authorizations on the same license are needed for the survey instrument calibration source/device and the calibration sources for the detection system for leakage/contamination testing. The licensee should have procedures for these uses.

Item 8.1: Sealed Sources and Devices or Unsealed Radioactive Material

Rule: 12VAC5-481-90, 12VAC5-481-150, 12VAC5-481-390, 12VAC5-481-420, 12VAC5-481-430, 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-480, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-520, 12VAC5-481-530, 12VAC5-481-840, 12VAC5-481-850, 12VAC5-481-860, 12VAC5-481-880, 12VAC5-481-3740, 12VAC5-481-3750

Criteria: An application for a license will be approved if the requirements of **12VAC5-481-440, 12VAC5-481-450,** and **12VAC5-481-480** are met. In addition, licensees will be authorized to possess and use only those sealed sources and devices that are specifically approved or registered by NRC or another agreement state.

Discussion: Each authorized radioisotope is listed on the VDH license by its element name, chemical and/or physical form, the maximum possession limit, and intended use. If a license of broad scope is being sought, also refer to VAREG ORH-720 H, 'Guidance for Broad Scope Licensees'.

The applicant should list each requested radioisotope by its element name and its mass number in the appropriate boxes on the application under Item 8.1. For volatile radioactive material, however, it is necessary to specify whether the requested radioisotope will be acquired in free (volatile) or bound (non-volatile) form, because additional safety precautions are required when handling and using volatile material. For example, when requesting authorization to possess and use iodine-125, the applicant must specify whether the material will be acquired in free or bound form. If a radioisotope will be acquired in both free and bound forms, then separate possession limits for each form must be requested. Applicants requesting an authorization to possess and use volatile radioactive material must provide appropriate facilities, engineering controls, and radiation safety procedures for handling such material.

If you plan to possess radioactive materials in excess of the quantities listed in **12VAC5-481-3740,** then you must provide with the application either: (1) an evaluation showing that the maximum off-site dose due to a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent (EDE) or 0.05 Sv (5 rem) to the thyroid; or (2) an emergency response plan for responding to the release in accordance with the criteria listed in **12VAC5-481-440 F**.

The anticipated possession limit in millicuries (mCi) (megabecquerels (MBq) or curies (Ci) (gigabecquerels (GBq) for each radioisotope should also be specified. Possession limits cover the total anticipated inventory, including licensed material in storage and waste, and should be commensurate with the applicant's needs and facilities for safe handling. If materials are expected or requested to be returned from customers, then these materials must be factored into the inventory. Applicants should review the requirements for submitting a certification for financial assurance for decommissioning before specifying possession limits of any radioisotope with a half-life greater than 120 days. These requirements are discussed in Section 8.2, Financial Assurance and Decommissioning.

A safety evaluation of sealed sources and devices is performed by NRC or another agreement state before authorizing a manufacturer (or distributor) to distribute them. The safety evaluation is documented in an SSD registration certificate. Information on SSD registration certificates may be obtained by calling the agency. Before formalization of the SSD registration process, some older sources or devices may have been specifically approved on a license. Licensees can continue to possess and use those sources and devices specifically listed on their licenses. Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that the agency can verify that they have been evaluated in an SSD registration certificate or specifically approved on a license.

Consult with the proposed supplier, manufacturer, or distributor to ensure that requested sources and devices are compatible with and conform to the SSD designations registered with the NRC or another agreement state. Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description of specifications from those indicted in the respective registration certificates, without obtaining VDH's prior permission in a license amendment. To ensure that applicants possess and use sources and devices according to registration certificates, they may want to get a copy of the certificate and review it or discuss it with the manufacturer.

Item 8.2: Financial Assurance and Record Keeping for Decommissioning

Rule: 12VAC5-481-100, 12VAC5-481-450 C, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-1161

Criteria: A licensee authorized to possess licensed material in excess of the limits specified in **12VAC5-481-450 C** must meet the requirements for decommissioning financial assurance.

All licensees are required to maintain, in an identified location, records of information important to decommissioning of the facility until the site, or any area, is released for unrestricted use. Licensees must transfer records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with **12VAC5-481-500** or to VDH before the license is terminated.

Discussion: VDH wants to ensure that decommissioning will be carried out with minimum impact on public and occupational health and safety and the environment. There are two parts to the rule: financial assurance that applies to SOME licensees, and recordkeeping that applies to ALL licensees.

VDH decommissioning financial assurance rules are designed to provide reasonable assurance that the decommissioning of licensed facilities will be accomplished in a safe and timely manner and that licensees will provide adequate funds. Applicants are required to submit financial assurance when the possession of radioactive material of a half-life of greater than 120 days exceeds certain limits. Criteria for determining whether an applicant is required to submit a Decommissioning Funding Plan (DFP) or has an option of submitting either a DFP or a Certificate of Financial Assurance (F/A) are stated in **12VAC5-481-450 C**. A DFP contains site-specific cost estimate and a certification of financial assurance. A Certification of Financial Assurance includes a certification that the licensee has provided the required financial assurance and an acceptable financial assurance instrument.

Acceptable financial assurance includes prepayment options (trusts, escrow accounts, government funds, certificates of deposit, or deposits of government securities); surety, insurance, or other guarantee methods (letters of credit, surety bonds, lines of credit, parent company guarantees, insurance policies); and statements of intent for Government entities. Refer to **12VAC5-481-450 C** for a table of required amounts of financial assurance for decommissioning by quantity of material.

NRC's NUREG-1727, "*NMSS Decommissioning Standard Review Plan"*, dated September 2000, provides guidance acceptable to VDH staff for the information to be provided for establishing financial assurance for decommissioning and a standard format for presenting the information. This NUREG also describes the information required to be submitted for a DFP.

The same regulation also requires that licensees maintain records important to decommissioning in an identified location. All sealed source licensees need to maintain records of structures and equipment where sealed sources are used or stored at locations specifically listed on the license. As-built drawings with modifications of structures and equipment shown as appropriate fulfill this requirement. If drawings are not available, licensees may substitute appropriate records concerning the areas and locations. In addition, if licensees have experienced unusual occurrences (e.g., leaking sources, other incidents that involve the spread of contamination), they also need to maintain records about contamination that remains after cleanup or that may have spread to inaccessible areas.

Requirements for Disposition of Records Important to Decommissioning

- Before licensed activities are transferred or assigned according to **12VAC5-481-500**, transfer to the new licensee.

OR

- Before the license is terminated, transfer records to VDH.

Reference: NRC Regulatory Guide 3.66 "*Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70 and 72*", is available from NRC at http://www.nrc.gov.

Item 8.3: Purpose(s) for Which Licensed Material Will Be Possessed and Used

Rule: 12VAC5-481-10, 12VAC5-481-450, 12VAC5-481-480, 12VAC5-481-500, **12VAC5-481-570, 12VAC5-571**

Criteria: Requested radioisotopes must be possessed and used for purposes authorized by **12VAC5-481,** 'Virginia Radiation Protection Regulations'. Sealed sources and devices containing licensed material must be possessed and used only for the purposes for which they are designed and according to manufacturer's (distributor's) instructions and recommendations for possession and use as specified in the SSD Registration Certificate.

In order to have a license for distribution of sources and devices containing radioactive materials, the applicant must first apply for and receive a Sealed Source and Device (SSD) registration from the NRC or another agreement state.

Note: If distributing sealed sources and devices to medical use licensees, also see **AppendixQ**, Medical Distribution.

Discussion: Applicants should clearly specify the purpose for which each radioisotope will be used. The description should be detailed enough to allow VDH to determine the potential for exposure to radiation and radioactive materials to those working with radioactive materials and members of the public.

Applicants should pay particular attention to the applicable regulations listed below when applying for a license to manufacture and distribute licensed material (see **Figure 1**). However, this list is not exhaustive, nor does it relieve the applicant from complying with applicable Federal, State and local

requirements. Applicants considering research and development can include the requested licensed materials in this application and should refer to VAREG ORH-720 F, 'Guidance for Research and Development and Other Licensees'. Applicants intending to possess and use licensed material for medical research involving humans must be authorized to do so pursuant to a license issued by the agency and should refer to VAREG ORH-720 G, 'Guidance for Medical Licenses'. Applicants intending to become a broad scope licensee should refer to VAREG ORH-720 H, 'Guidance for Broad Scope Licenses' for instructions.

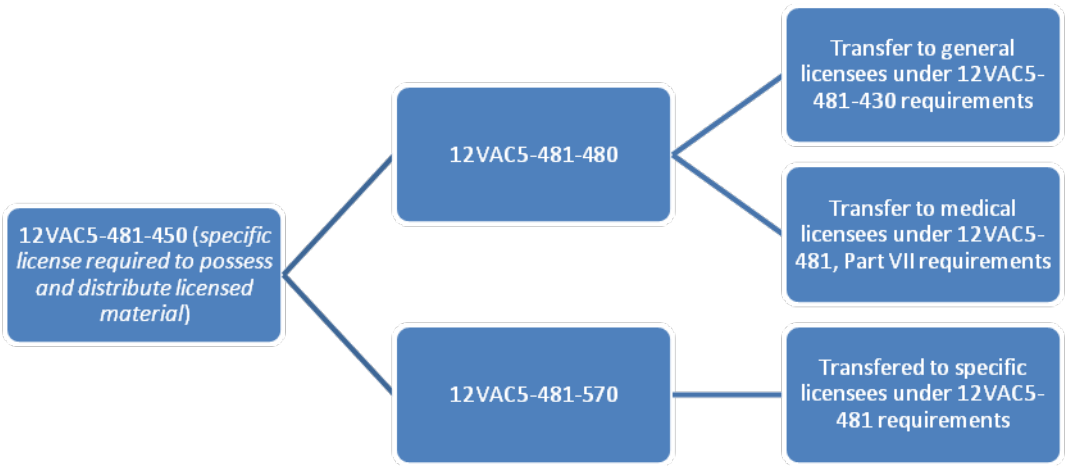


Figure 1: License Requirements.

Applicants should clearly specify if the licensed material will be used in animal studies and/or tracer studies as part of manufacturing. Use of licensed material in animals may be in quality control or research studies. Applicants should also state whether the studies will be limited to small animals (e.g. rats, mice) or may also include larger animals (e.g., pigs, dogs, horses). See VAREG ORH-720 G, 'Guidance for Research and Development and Other Licenses'.

Applicants for medical distribution licenses must refer to **12VAC5-481-480 I** and **J**, in addition to the guidance specified in **Appendix Q**.

Some "manufacturers" are importers of materials and devices from abroad and do not require the same extent of information submission and review as a facility that produces an item. However, they are required to have a manufacturer/distributor license as the initial importer and distributor in the United States. The device distributor may be the sponsor of the SSD registration certificate. The manufacturer/distributor license is separate from the "G" or "E" distribution license.

The general distribution only license and the exempt distribution only license application requirements are not covered in this document. Applicants for these licenses are referred to NRC's NUREG-1556, Vol. 16, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees," and NRC's NUREG-1556, Vol. 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance about Exempt Distribution Licenses."

Note: Applicants intending to manufacture sealed sources or devices should refer to **Item 10.2** for sealed source and device licensing criteria for evaluation of design and construction.

Item 9: Facilities and Equipment

Rule: 12VAC5-481-450, 12VAC5-481-480, 12VAC5-481-630, 12VAC5-481-730, 12VAC5-481-840

Criteria: 12VAC5-481-450 states that an application will be approved if the applicant's proposed equipment and facilities are adequate to protect health and to minimize danger to life or property. They must minimize the possibility of contamination and keep exposures to workers and the public ALARA. **12VAC5-481-840** states that licensed material stored in an unrestricted area must be secured from unauthorized removal, and licensed materials in an unrestricted area and not in storage must be under the constant surveillance and immediate control of the licensee.

Discussion: Applicants must demonstrate that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and its employees, keep exposures to radiation and radioactive materials ALARA, and minimize the danger to life and property from uses of the types and quantities of radioactive materials.

Applicants may delay completing facilities and acquiring equipment until after the application review is completed, in case changes are required as a result of the application review. This also ensures the adequacy of the facilities and equipment before the applicant makes a significant financial commitment. In all cases, the applicant may not possess or use licensed material until after the facilities are approved, equipment is procured, and the license is issued.

Applicants are reminded that records important to decommissioning include the following:

- As-built drawings and modifications of structures and equipment in restricted areas;
- As-built drawings and modifications of locations of possible inaccessible contamination such as buried pipes that may be subject to contamination;
- Records of spills and unusual occurrences that may result in contamination of the facility or site.

These records are required to be maintained in an identifiable location. Facilities are required to meet VDH criteria prior to release. Therefore, careful facility design is important to prevent contamination, or facilitate decontamination, reducing the costs needed for decommissioning.

Provide the following on the facility diagrams, as shown in **Figure 2**:

- Drawings should be to scale, and indicate the scale used;
- Location, room numbers, and principal use of each room or area where radioactive material is prepared, used or stored;
- Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below; indicate whether the room is a restricted or unrestricted area as defined in **12VAC5-481-10**;
- Provide shielding calculations and include information about the type, thickness and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used (e.g., source storage safe, etc.); and
- If multiple locations of use or storage, indicate address on diagram.

For additional guidance regarding facilities and equipment, refer to **Appendix F**, Facilities and Equipment.

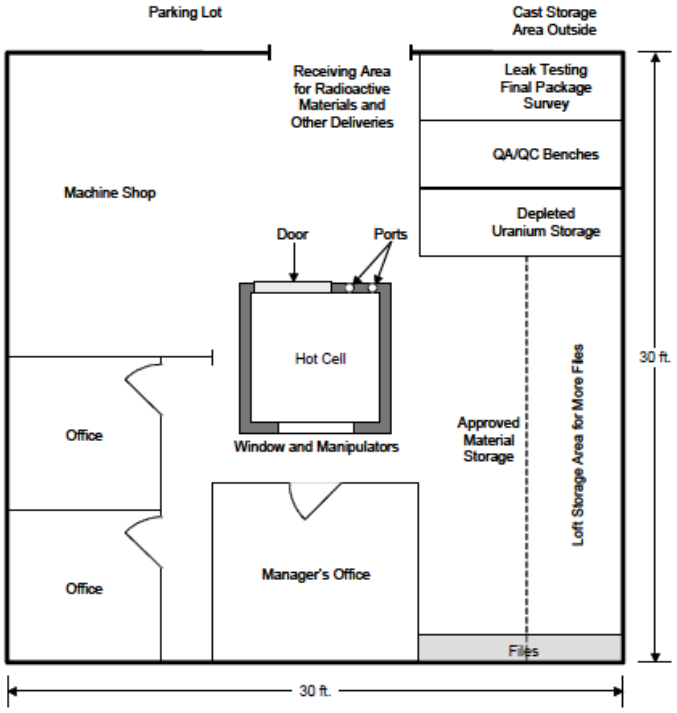


Figure 2: Facility Diagram.

Radiation Safety Program

Item 10: Radiation Safety Program

Item 10.1: Audit Program

Rule: 12VAC5-481-450, 12VAC5-481-630, 12VAC5-481-990

Criteria: Licensees must review the content and implementation of their radiation protection programs annually to ensure the following:

- Compliance with VDH and DOT regulations, and the terms and conditions of the license;
- Occupational doses and doses to members of the public are as low as reasonably achievable (ALARA) **(12VAC5-481-630)**; and
- Records of audits and other reviews of program content are maintained for 3 years.

Discussion: Appendix G contains a suggested audit program that is acceptable to VDH. All areas indicated in **Appendix G** may not be applicable to every licensee and may not need to be addressed during each audit. Conversely, other licensee specific activities may need to be added to the form.

Currently the agency's emphasis in inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of users throughout the manufacturing process to determine if, for example, operating and emergency procedures are available, are being followed, etc.

It is essential that once identified, problems be corrected comprehensively and in a timely manner; NRC Information Notice (IN) 96-28, "*Suggested Guidance Relating to Development and Implementation of Corrective Action*", provides guidance on this subject. The agency will review the licensee's audit results

and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. If violations are identified by the licensee and these steps are taken, the agency can exercise discretion and may elect not to cite a violation. The agency's goal is to encourage promote identification and prompt, comprehensive correction of violations and deficiencies.

With regard to audit records, **12VAC5-481-990** requires licensees to maintain records of audits and other reviews of program content and implementation. The agency has found audit records that contain the following information to be acceptable: date of audit, name of person(s) who conducted audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up.

Item 10.2: Radiation Monitoring Instruments

Rule: **12VAC5-481-450, 12VAC5-481-730, 12VAC5-481-740, 12VAC5-481-750, 12VAC5-481-900, 12VAC5-481-930, 12VAC5-481-1000**

Criteria: Licensees must possess radiation monitoring instruments that are necessary to protect health and minimize danger to life or property. Instruments used for quantitative radiation measurements must be calibrated periodically for the radiation measured.

Discussion: Licensees shall possess calibrated radiation measurement instruments to perform, as necessary, the following:

- Package surveys
- Sealed source leak tests
- Personnel and facility contamination measurements
- Air sampling measurements
- Bioassay measurements
- Effluent release measurements
- Dose rate surveys

For the purposes of this document, survey instruments are defined as any device used to measure the radiation exposure or contamination levels at a licensed facility. Survey instruments that may be used to perform these measurements include exposure rate meters or contamination survey meters, single or multichannel analyzers, liquid scintillation counters, etc. Survey instruments that will be available for use should be listed and descriptions provided. The description should include type of instrument and detector and its intended purpose.

Instruments used for qualitative surveys are only intended to detect contamination. Such instruments should be checked for operational response with an appropriate check source containing radioactive material, and can be calibrated with an electronic pulsar instead of a radioactive source. However, these instruments cannot be used for measurement of surface contamination or radiation levels without a calibration with appropriate radioactive sources, as described in **Appendix H**.

VDH requires that calibrations be performed by the instrument manufacturer or a person specifically authorized by VDH, NRC, or another Agreement State. Applicants seeking authorization to perform survey instrument calibrations shall submit procedures for review. **Appendix H** provides information about instrument specifications, calibration procedures and air sampler program.

Item 10.3: Material Receipt and Accountability

Rule: 12VAC5-481-10, 12VAC5-481-100, 12VAC5-481-390, 12VAC5-481-400, 12VAC5-481-410, 12VAC5-481-420, 430, 12VAC5-481-450, 12VAC5-481-480, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-750, 12VAC5-481-840, 12VAC5-481-900, 12VAC5-481-910, 12VAC5-481-980, 12VAC5-481-1060, 12VAC5-481-1080, 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1130, 12VAC5-481-1150, 12VAC5-481-1151, 12VAC5-481-3730

Criteria: Licensees must do the following:

- Develop, implement and maintain procedures for opening packages and ensuring security and accountability of licensed materials;
- Maintain records of receipt, transfer, and disposal for all sealed sources; and
- Conduct physical inventories at intervals not to exceed 6 months (or some other interval justified by the applicant) to account for all sealed sources.

Discussion: Licensees are required to develop, implement, and maintain written procedures for safely opening packages in accordance with **12VAC5-481-900**. Some packages may require special procedures that take into consideration the type, quantity, or half-life of the nuclide being delivered. Licensees need to make arrangements to receive radioactive packages when they are delivered or to be notified when the packages arrive at the carrier's terminal, so that the licensee can pick up the package expeditiously. A model for safely opening packages containing licensed material can be found in **Appendix I**. VDH regulations in **12VAC5-481-900** state the requirements for monitoring packages containing licensed material. These requirements are described in **Table 3**.

Table 3: Package Monitoring Requirements

Package	Contents	Survey Type	Survey Time*
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Greater Than Type A	Radiation Level	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Not Gas Nor Special Form Greater Than Type A	Contamination Radiation Level	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Less Than Type A	None	None
Labeled (White I, Yellow II, Yellow III)	Not Gas Nor Special Form Less Than Type A	Contamination	As soon as practicable, but not later than 3 hours after receipt of package
Not Labeled	Licensed Material	None	None
Damaged	Licensed Material	Contamination Radiation Level	As soon as practicable, but not later than 3 hours after receipt of package

* Assumes packages are received during normal working hours. If packages are received outside of normal working hours, the licensee has three hours after the beginning of the next work day to perform the required surveys.

Note: Additional information on DOT regulations is contained in this VAREG in **Item 10.10** and **Appendix O**.

Licensees are required to maintain records of receipt, transfer, and disposal of licensed material. Loss, theft, or misplacement of radioactive material can occur; therefore control and accountability of sealed sources must be ensured. Licensees who use and/or possess sealed sources are required by license conditions to perform inventories of sealed sources every six months. Sealed sources that are not in use may be placed in storage and shall be inventoried at least every 6 months.

Inventory records should be maintained and contain the following types of information:

- Radionuclide and amount (in units of becquerels or curies) of radioactive material in each sealed source;
- Manufacturer's name, model number, and serial number (if appropriate) of each device containing radioactive material;
- Location of each sealed source and device;
- Date of the inventory; and
- Signature or initials of the individual performing the inventory; and
- For materials transferred or disposed of, the date of the transfer or disposal, name and license number of the recipient, description of the affected radioactive material (e.g., radionuclide, activity, manufacturer's (or distributor's) name and model number, serial number).

VDH must be notified when licensed material is lost or stolen. The RSO must be proactive in evaluating whether VDH notification is required. Refer to **Appendix O** and the regulations (**12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1130, 12VAC5-481-1150,** and **12VAC5-481-1151**) for a description of when and where notifications are required.

'Cradle to Grave' Accountability refers to maintaining the radioactive material from the moment it becomes a part of your organization (whether through creation there, delivered to company, etc) through performing the quarterly inventories (ensuring the material's location, etc) until it leaves your organization (through shipment, disposal on/off site, etc)

Accountability for Materials Not Included in the Manufactured Products

Licensees frequently possess radioactive material, which is generally licensed or distributed to them as an exempt quantity in addition to that which is specifically listed on their license. **12VAC5-481-430** provides information regarding generally licensed devices. Any person who acquires, receives, possesses, uses, or transfers a generally licensed device must do so in accordance with the provisions of the general license. Generally licensed material possessed by a specific licensee may continue to be possessed under a general license. A specific license does not automatically remove general licensee status nor automatically move generally licensed material to the specific license. VDH recognizes that multiple authorizations can create some confusion and, therefore, a specific licensee always has the option of receiving and possessing radioactive materials that qualify for a general license by adding these to the specific license.

Similarly, radioactive material received by a specific license, which is distributed to them under an exemption from the requirements for a license, is not subject to the terms and conditions of the specific license. Any person may receive radioactive material that is exempt from the requirements of a license pursuant to the regulations in **12VAC5-481-390** and **12VAC5-481-400**. Such materials may include exempt quantities of radioactive materials which do not exceed the applicable quantity listed in **12VAC5-481-3730**, as well as items such as smoke detectors and self-luminous watches, which are distributed in accordance with other VDH regulations. Most licensees do not possess or control these types of devices under the provisions of their specific license and VDH does not require or encourage this practice; however, as stated above, the specific licensees have the option of adding these materials to its license and controlling them under the conditions of the specific license. In any case, licensees are required to ensure

that dose limits are not exceeded, whether or not the dose results from licensed sources or unlicensed sources.

Accountability for Materials Included in the Manufactured and Distributed Products

Licensees who use and/or possess sealed sources are required by license condition to perform inventories of sealed source every 6 months. Some sealed sources may not be in use or are rarely used and are placed in storage. In these cases, licensee should, at least every 6 months, confirm that these sealed sources have not been distributed. Licensees are also required to conduct leak tests of sealed sources, not in storage, at 6-month intervals (or at longer intervals as specified in the SSD Registration Certificate). Since the leak tests require an individual to locate and work with sealed sources, records of leak tests may be used as part of an inventory and accountability program.

With regard to unsealed licensed material, licensees use various methods (e.g., computer programs, manual ledgers, log books) to account for receipt, use, transfer, disposal, and radioactive decay. These methods help to ensure that possession limits are not exceeded.

To ensure that only trained, experienced and authorized individuals possess or possess and use or supervise the possession or possession and use of licensed material, the RSO should know who has requested an order of licensed material and the types and amounts of licensed materials requested. Control procedures should also be established for the procurement of licensed materials that may be obtained outside normal channels (e.g., through the loan or other transfer of materials without purchase, or through surplus). A model procedure for ordering and receiving radioactive material is included in **Appendix I**.

VDH regulations applicable to transfers are stated in **12VAC5-481-570**. Sample policy transfer statements are included in **Appendix I**. Transfer of licensed materials within the facility may require special procedures to ensure proper control. In many facilities, pieces of laboratory equipment or components may become contaminated. Surveys of and removal of these items for maintenance, repair, or disposal should also be carefully controlled.

Licensees must maintain records of receipt, use, transfer, and disposal of all licensed material. **Table 3** lists each type of record and how long the record must be retained. Other records, such as transfer records, could be linked to radioactive material inventory records. Receipt records should also document cases where excessive radioactive levels or contamination were found on packages or containers of material received and describe the action taken.

Manufacturers/distributors must also make reports to regulatory agencies for exempt and general licensed devices distributed so that these can be accounted for and registered in some cases. Please refer to NRC's NUREG-1556, Vol. 8, "*Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses,*" and NUREG-1556, Vol. 16, "*Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees*."

Table 4. Record Maintenance

Type of Record	How Long Record Must be Maintained
Receipt	For as long as the material is possessed until 3 years after transfer or disposal
Transfer	For 3 years after transfer
Disposal	Until VDH terminates the license
Important to decommissioning	Until the site is released for unrestricted use

Receipt, transfer, and disposal records typically contain the following information:

- Radionuclide and activity (in units of becquerels or curies) and date of measurement
- For each sealed source, manufacturer, model number, location and, if needed for identification, serial number, and, as appropriate, manufacturer and model number of device containing the sealed source
- Date of the transfer and the name and license number of the recipient and description of the affected radioactive material (e.g., radionuclide, activity, manufacturer's name and model number, serial number)
- For licensed materials disposed of as waste, include the radionuclide, activity, date of disposal, and method of disposal (decay, sewer, etc.)

See **Item 10.12**, Waste Management, for additional information.

Note:

- No response is needed from applicants for package opening procedures. These procedures will be reviewed during inspection.
- Alternative responses will be evaluated using the criteria listed above.

Item 10.4: Occupational Dosimetry

Rule: 12VAC5-481-10, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-650, 12VAC5-481-660, 12VAC5-481-670, 12VAC5-481-680, 12VAC5-481-700, 12VAC5-481-710, 12VAC5-481-750, 12VAC5-481-760, 12VAC5-481-830, 12VAC5-481-990, 12VAC5-481-1000, 12VAC5-481-1020, 12VAC5-481-1030, 12VAC5-481-1040, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1120, 12VAC5-481-1130, 12VAC5-481-1140, 12VAC5-481-2260, 12VAC5-481-2270, 12VAC5-481-3690

Criteria: Applicants must do either of the following:

- Provide dosimetry processed and evaluated by a National Voluntary Laboratory Accreditation Program (NVLAP) approved processor that is exchanged at a frequency recommended by the processor.

OR

- Maintain, for inspection by VDH, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits as shown in **Table 5** and **Table 6**, respectively, and individuals will not be entering a high radiation area.

Table 5: Occupational Dose Limits For Adults

Occupational Dose Limits for Adults (12VAC5-481-640)	
Body Location	Dose (Annual)
Total Effective Dose Equivalent (TEDE)	0.05 Sv (5 Rem)
Dose to the skin of the whole body or any extremity*	0.5 Sv (50 Rem)
Dose to lens of the eyes	0.15 Sv (15 Rem)
*Extremities includes the arms below the elbows and the legs below the knees	

Table 6: Internal Exposure Limits

Internal Exposure Limits (12VAC5-481-640)	
Individual	Dose
Adults	Likely to receive in 1 year an intake in excess of 10% of the applicable ALI* for ingestion and inhalation
Minors	Likely to receive in 1 year a CEDE** in excess of 1 mSv (0.1 rem)
Declared Pregnant Woman	Likely to receive, during entire pregnancy, a CEDE** in excess of 1 mSv (0.1 rem)
*ALI = Annual Limit on Intake **CEDE = Committed Effective Dose Equivalent	

Discussion: According to **12VAC5-481-760**, if an adult is likely to receive in one year a dose greater than 10% of any applicable limit (see **Table 5**), monitoring for occupational exposure is required. The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose. These evaluations need not be made for every individual; evaluations can be made for employees with similar job functions or work areas. For individuals who have received doses at other facilities in the current year, the previous dose need not be considered in this prospective evaluation. Further guidance on evaluating the need to provide monitoring is provided in NRC Regulatory Guide 8.34, "Monitoring Criteria and methods to Calculate Occupational Doses." If the prospective dose evaluation shows that the individual is likely to exceed 10% of a regulatory limit, monitoring is required. Recordkeeping of the results of monitoring performed, regardless of the actual dose received, is required by **12VAC5-481-1040**.

Licensee are required to provide individual radiation exposure data to each worker annually and as otherwise described in **12VAC5-481-2270**.

A common method for dose evaluation is to monitor workers' dose with whole body and extremity dosimetry (TLDs, film, OSL, etc) provided by a National Voluntary Laboratory Accreditation Program (NVLAP)-approved dosimetry service. If these devices are used, the licensee is responsible for exchanging and processing them in a timely manner. Also, the licensee is responsible for ensuring that dosimetry results are assigned accurately and should consider that the assigned deep-dose equivalent and

shallow-dose equivalent must be the part of the body receiving the highest exposure. Therefore, if possible, whole body and extremity dosimeters should be placed in the areas that receive the highest exposure. An evaluation must be performed to determine if the maximum dose to a part of the whole body or an extremity may be substantially higher than the dose measured by the dosimeter. If the evaluation indicates that the maximum dose to a part of the whole body or extremity is higher than that measured by the dosimeter, the higher dose will be used as the dose of record.

Workers are typically monitored for a year or more to determine actual annual dose. The monitoring results are then used to determine the need to continue monitoring workers. The dose to workers may need to be reevaluated if there are changes to the licensee's program, such as procedures, frequency of use, quantity of licensed material used, isotopes used, etc. The licensee should also consider a more frequent exchange of dosimeters when employees start a new job function, so that their doses can be closely monitored when they are performing unfamiliar tasks. In addition, see **Appendix M** for information on bioassay monitoring for internal exposure assessment.

Licensees who do provide personnel monitoring use either film badges, optically stimulated luminescent (OSLs) dosimetry or thermoluminescent dosimeters (TLDs) that are supplied by a NVLAP-approved processor. Applicants should verify that the processor is NVLAP-approved. Consult the NVLAP-approved processor for its recommendations for exchange frequency and proper use.

Reference: National Institute of Standards and Technology (NIST) Publication 810, "*National Voluntary Laboratory Accreditation Program Directory*", is published annually and is available for purchase from United States Government Printing Office and on the Internet at the following address: http://nvl.nist.gov/

Item 10.5: Public Dose

Rule: 12VAC5-481-10, 12VAC5-481-630, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-840, 12VAC5-481-1050, 12VAC5-481-1110, 12VAC5-481-3070

Criteria: Licensees must do the following:

- Ensure that licensed material will be possessed, used, transported, stored, and disposed in such a way that members of the public will not receive more than 1 millisievert (100 millirem) in one year, and the dose in any unrestricted area will not exceed 0.02 millisievert (2 millirem) in any one hour, from licensed operations.
- Ensure that air emissions of radioactive material to the environment will not results in a TEDE (Total Effective Dose Equivalent) in excess of 10 millirem (0.1 mSv) per year to individual members of the public.
- Ensure that the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour, from licensed operations;
- Control and maintain constant surveillance over licensed material that are not in storage and secure licensed material from unauthorized removal or use.

Discussion: "*Public dose*" is defined in **12VAC5-481-10** as "*the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee"*. Public dose excludes doses received from background radiation and from medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individuals assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) the individual is in when the dose is received.

Members of the public include persons who live, work, or may be near locations where licensed materials are used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where licensed materials are used or stored.

There are many possible internal dose pathways that contribute to the TEDE. The TEDE can, however, be broken down into three major dose pathway groups:

- Airborne radioactive material
- Waterborne radioactive material
- External radioactive exposure

The licensee should review these major pathways and decide which are applicable to its operations. For guidance about accepted methodologies for determining dose to members of the public, please refer to **Appendix J**.

Operating and emergency procedures regarding security and surveillance specified under that section of this document should be sufficient to limit the exposure to the public during use or storage and after accidents. Public dose is controlled, in part, by ensuring that licensed materials not in use are stored securely (e.g., stored in a locked area) to prevent unauthorized access or use. If licensed materials are not in storage, then authorized users must maintain constant surveillance to ensure that members of the public, who could be co-workers, cannot get near the licensed materials and thus receive unnecessary radiation exposure.

Public dose is also affected by the choice of storage location and conditions. Licensees can determine the radiation levels adjacent to the storage location either by calculations or a combination of direct measurements and calculations. If, after making an initial evaluation, a licensee makes changes affecting the storage area (location change, isotope, activity used, etc.), then the licensee must ensure that licensed materials are properly secured, perform a new evaluation to ensure that the public dose limits are not exceeded, and take corrective action, as needed.

Item 10.6: Operating and Emergency Procedures

Rule: 12VAC5-481-450, 12VAC5-481-480, 12VAC5-481-490, 12VAC5-481-630, 12VAC5-481-740, 12VAC5-481-750, 12VAC5-481-840, 12VAC5-481-850, 12VAC5-481-860, 12VAC5-481-870, 12VAC5-481-880, 12VAC5-481-890, 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1120, 12VAC5-481-1130, 12VAC5-481-1140, 12VAC5-481-1151, 12VAC5-481-2260, 12VAC5-481-2280, 12VAC5-481-3740

Criteria: Operating and emergency procedures must be developed to minimize risks of loss or theft as well as to ensure safe use of radioactive material. The agency considers security of sealed sources extremely important and lack of security is a significant violation for which licensees are fined.

Discussion: Operating and emergency procedures shall contain the following elements:

- Contamination controls
- Waste disposal practices
- Personnel and area monitoring (including limits)
- Use of protective clothing and equipment
- Safe handling of radioactive materials
- Recordkeeping requirements
- Reporting requirements

These procedures should address licensee policies such as frequency of personnel monitoring, use of appropriate shielding, and frequent changing of gloves to minimize exposure and avoid the spread of contamination. These procedures should be product and radioisotope-specific. General safety guidelines are described in **Appendix K**. Applicants should use these guidelines to develop procedures for the safe use of radioisotopes.

Licensee should determine if they have areas that require posting in accordance with **12VAC5-481-860**, unless they meet exemptions listed in **12VAC5-481-870**. Also containers of licensed material (including radioactive waste) must be labeled in accordance with **12VAC5-481-880**, unless they meet exemptions listed in **12VAC5-481-890**.

Notify the agency when sealed sources are lost or stolen. Refer to **12VAC5-481-1090, 12VAC5-481-1100,** and **12VAC5-481-1110** for a description of when and where notifications are required.

Security Procedures

All licensed materials that are stored in controlled or unrestricted areas must be secured from unauthorized access or removal, so that individuals who are not knowledgeable about radioactive materials cannot be exposed to or contaminated by the material, and cannot take the material. When any licensed materials are in use in controlled or unrestricted areas, they must be under constant surveillance so that the radiation worker can prevent others from becoming contaminated by or exposed to the material, or to prevent unauthorized individuals from removing the material. Acceptable methods for securing material will vary from one facility to another. Some alternatives used by licensees include: storage and use of licensed materials only in restricted areas; limiting access to an entire facility or building or portion of the building only to radiation workers; providing storage areas that can be locked to prevent access to the material; and implementing procedures that require a radiation worker to be within line of sight of the materials whenever licensed materials are in use. Applicants should develop procedures that clearly state acceptable methods to secure licensed material in their facility. Particular attention may need to be paid to security procedures at facilities which may have unusual needs due to activities performed, such as hot cells, animal care facilities, and waste processing facilities.

Emergency Procedures

Accidents and emergencies can happen during any operation with radioisotopes, including their transportation, use, production processes, transfers, and disposal. Such incidents can result in contamination or release of material to the environment, and unintended radiation exposure to workers and members of the public. In addition, loss or theft of licensed material, sabotage, fires, floods, etc., can jeopardize the safety of personnel and members of the public. It is therefore necessary to develop written procedures to minimize, as much as possible, the impact of these incidents on personnel, members of the public, and the environment. Applicants who plan to possess quantities of material in excess of the applicable amounts listed in **12VAC5-481-3740** may also be required to submit an emergency response plan.

Applicants should establish written procedures to handle events ranging from minor spill to a major accident that may require intervention by outside emergency response personnel. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of users and the radiation safety staff. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, the licensee staff should have a clear understanding of their limitations in an emergency, along with step-by-step instructions and clear guidelines for whom to contact.

Licensees should have a sufficient number of appropriate and calibrated survey instruments readily available. Emergency spill kits should be strategically placed in well-marked locations with items

appropriate for the types of use and accessible by the radiation safety staff. All equipment should be periodically inspected for proper operation and replenished as necessary. **Appendix K** includes model emergency procedures. Applicants may adopt these procedures or develop their own, incorporating the safety features included in these model procedures.

Note: If an emergency response plan is required for your license pursuant to **12VAC5-481-440 G**, submit this plan with your application.

Item 10.6.1 : License Verification and Information

Rule: 12VAC5-481-570

Criteria: Licensees are required by **12VAC5-481-570** to verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

Discussion: Prior to the transfer, distribution, or redistribution of any licensed material, the manufacturer/distributor must verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. The manufacturer/distributor should verify that the address to which radioactive materials are delivered is an authorized location of use listed on the customer's license. **12VAC5-481-570** lists five methods that can be used to meet the license verification requirement. The most common form of verification is for the manufacturer/distributor to possess a valid copy of the customer's VDH, NRC, or another Agreement State license or other applicable document (e.g. *in vitro* registration VDH form, 'Certificate – In Vitro Testing With Radioactive Material Under General License').

As the manufacturer/distributor you should provide the transferee with information regarding the regulatory requirements of the radioactive material being transferred. This information should include leak testing requirements, dosimetry requirements, disposal options, etc. Submit this information with the application for review.

Item 10.7: Surveys

Rule: 12VAC5-481-180, 12VAC5-481-630, 12VAC5-481-720, 12VAC5-481-740, 12VAC5-481-750, 12VAC5-481-1000, 12VAC5-481-1010, 12VAC5-481-1150

Criteria: Licensees are required by **12VAC5-481-750** to make surveys of potential radiological hazards in their workplace. Records of surveys and leak test results must be maintained.

Discussion: A survey is defined in **12VAC5-481-10** as, *"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."* These evaluations of radiological conditions and potential hazards may be measurements (e.g., radiation levels measured with survey instruments or results of wipe tests for contamination), calculation, or a combination of measurements and calculations. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess the radiological conditions. In order to meet regulatory requirements for surveying, measurements of radiological quantities should be understood in terms of their properties (i.e., alpha, beta, gamma) and compared to the appropriate limits.

Radiation surveys are used to detect and evaluate contamination of:

- Facilities;
- Equipment;
- Personnel;
- Restricted and unrestricted areas;
- Packages;
- Products produced.

Surveys are also used to plan work in areas where licensed material or radiation exists and to evaluate doses to workers and individual members of the public.

12VAC5-481-750 states that surveys are required when it is reasonable under the circumstances to evaluate a radiological hazard, and as necessary, for the licensee to comply with the regulations. Many different types of surveys may need to be performed due to particular use of licensed material. The most important are as follows:

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, production line, packages, and equipment.
- Measurements of radioactive material concentration in air for areas where radioactive materials are handled or processed in unsealed form, and where operations could expose workers to the inhalation of radioactive material, or where licensed material is, or could be, released to unrestricted areas.
- Measurements of radioactive material concentrations in water that is released to the environment or to the sanitary sewer.
- Bioassays to determine the kinds, quantities, or concentration, and in some cases, the location of radioactive material in the human body. A bioassay can be made by direct measurement (*in vivo* counting), or by analysis and evaluation of material excreted or removed from the human body (*in vitro* counting).
- Surveys of external radiation exposure levels in both restricted and unrestricted areas.

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect the worker from external and internal exposure. Also, the frequency of the survey depends on the type of survey (see **Appendix M**).

Not all instruments can measure a given type of radiation. The presence of other radiation may interfere with a detector's ability to measure the radiation of interest. Correct use of radiation detection and measurements is an important aspect of any radiation safety program. **Table 8** in **Appendix H** contains radiation monitoring and survey instruments and calibration programs that are acceptable to VDH.

12VAC5-481, Part IV does not specify limits for surface contamination. Each applicant should propose and justify what removable surface contamination limits will be allowable before decontamination will be performed in each work area. Contamination checks are required before distributing fabricated sources. **Table 12** in **Appendix M** contains contamination limits that are acceptable to VDH.

Item 10.8: Leak Tests

Rule: 12VAC5-481-180, 12VAC5-481-740, 12VAC5-481-750, 12VAC5-481-1000, 12VAC5-481-1010, 12VAC5-481-1150

Criteria: VDH requires testing to determine whether there is any radioactive leakage from sealed sources. Records of leak test results are to be maintained.

Discussion: A licensee will be required to ensure performance of leak tests at intervals approved by the NRC or another Agreement State and as specified by the SSD registration certificate. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 μCi) of radioactivity.

Manufacturers, consultants, and other organizations may be authorized by VDH, NRC, or another Agreement State either to perform the entire leak test sequence for other licensees or to provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample according to the sealed source manufacturer's (distributor's) and the kit supplier's instructions and return it to the kit supplier for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. Licensees may also be authorized to conduct the entire leak test sequence themselves by adopting the procedures in **Appendix N** or submitting alternative procedures.

Leak tests are not required if:

- Sources contain only H-3;
- Sources contain only licensed material with a half-life less than 30 days;
- Sources contain only a radioactive gas;
- Sources contain 3.7 MBq (100 μCi) or less of beta-emitting or gamma-emitting material or 370 kBq (10 μCi) or less of alpha-emitting material; or
- Sources are stored and not being used (must be leak tested every 5 years and before use or transfer)

From more information regarding leak tests, see **Appendix N**.

Service Licensee

If a licensee wants to perform leak tests for its customers, it must obtain a service license. This may also be accomplished by amending an existing license. For more information regarding service license applications, see NRC's NUREG-1556, Vol. 18.

Note: If a sealed source or plated foil is added to an existing license that license might already authorize the licensee to perform the leak test sequence. In this case, the licensee may perform the leak testing on the sealed source or plated foil according to procedures previously approved on its license.

Item 10.9: Maintenance

Rule: 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-630

Criteria: Maintenance of devices and facilities that use radioactive materials is necessary. Maintenance should be planned and carried out as frequently as needed, using ALARA principles. Individuals performing maintenance should be training in the procedures they implement. Procedures should be written to account for the skills of the implementing personnel. Ordinarily, individuals handling unshielded materials should have up to forty hours of classroom and on-the-job training in radiation safety. Instructors should be more extensively qualified than the staff they teach.

Discussion: Maintenance of equipment and facilities is necessary in order to produce a quality product safely and efficiently and to ensure a safe environment for staff and the public. Manufacturing a product incorporating radioactive materials is an additional hazard, requiring attention to detail when

incorporating maintenance information into procedures. Licensee staff should ensure that materials in the process stream are properly shielded/located/protected to minimize the hazard to maintenance staff. Maintenance staff should be aware of the hazards and the procedures to minimize their exposure to radioactive materials that are possessed and used to control the manufacturing process. As examples: (1) a radioisotope hot cell should have its contents moved or shielded before any maintenance requiring entry is begun, and the staff should survey the hot cell working area prior to entry; and (2) a maintenance procedure should direct the shutdown and lockout of applicable process control gauges before beginning work in the area, which may be in direct beam of the gauges, whether inside the process vessel, or outside the vessel**.** Maintenance procedures should be prepared with the use of engineering controls first, using ALARA principles and administrative controls, as needed.

Item 10.10: Transportation

Rule: 12VAC5-481-100, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-2970, 12VAC5-481-2980, 12VAC5-481-2990, 12VAC5-481-3000, 12VAC5-481-3010, 12VAC5-481-3020, 12VAC5-481-3030, 12VAC5-481-3040, 12VAC5-481-3051, 12VAC5-481-3070, 12VAC5-481-3080, 12VAC5-481-3100, 12VAC5-481-3130, 49 CFR Parts 171-178

Criteria: Applicants who will transport or ship licensed material, including radioactive waste, must develop, implement, and maintain safety programs for public transport of radioactive material to ensure compliance with VDH, NRC, and DOT regulations.

Discussion: Packages shipped by licensees frequently meet the "*Limited Quantity*" criteria described in **49 CFR 173.421** and therefore could be exempt from certain DOT requirements. However, they may be subject to other, less restrictive, DOT requirements (e.g., **49 CFR 13.422 and 173.424**; also see **Appendix O** for more information).

If they are not exempted, however, licensed material, including radioactive waste, must be packaged and transported in accordance with VDH, NRC, and DOT requirements if the transportation involves common carriers or the use of public highways. Licensees should develop and maintain their own radiation safety procedures for transporting licensed material within their own facilities if it does not involve the use of public highways. (See NRC's NUREG-1660/RAMREG-002, "*U.S.-Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments*".)

Licensees should consider the safety of all individuals who may handle or come into contact with the packages containing licensed material. Therefore, the primary considerations in packaging licensed material should be to ensure that package integrity is not compromised during transport and that radiation levels (including removable contamination levels) at the package surfaces not only meet the regulatory requirements of **12VAC5-481-3080**, but are ALARA.

All domestic shipping papers and labels must be in SI units only OR must be in SI units first, with English units in parenthesis.

Licensees shipping radioactive waste for disposal must prepare appropriate documentation.

The general license in **12VAC5-481-2990** provides the authorization used by most licensees to transport, or offer for transport, packages of radioactive material and specifies certain conditions. Transporting licensed materials originating at some facilities involves quantities of radioactive material that require a Type B package. The manufacturer (or service licensee) who is subject to the provisions of **12VAC5-481-2990** or **12VAC5-481-3000**, as appropriate, is responsible for proper packaging of the radioactive

materials and compliance with VDH, NRC, and DOT regulations. Licensees who use another manufacturer's Type B packaging must ensure that other manufacturer (or service licensee):

- Is authorized to possess the licensed material at temporary job sites;
- Actually takes possession of the licensed material under its license;
- Uses an appropriate Type B package;
- Is registered with NRC as a use of the Type B package;
- Has an NRC approved QA plan.

For each shipment, it must be clear who possesses the licensed material and is responsible for proper packaging of the radioactive materials and compliance with VDH, NRC, and DOT regulations.

If a licensee plans to make shipments of licensed materials in Type B package on its own, the licensee must be registered as a user of the package and have an agency approved quality assurance (QA) plan, two of the requirements under the **12VAC5-481-2990** general license. For information about QA plans, see Revision 1 of NRC Regulatory Guide 7.10.

Item 10.11: Minimization of Contamination

Rule: 12VAC5-481-450, 12VAC5-481-630, 12VAC5-481-510, 12VAC5-481-1161

Criteria: Applicants for new licenses must describe 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 fullest extent practicable, the generation of radioactive waste.

Discussion: When designing facilities and developing procedures for their safe use, applicants should think ahead and consider how to minimize radioactive contamination/decontamination during operating and during decommissioning efforts, and how to minimize radioactive waste generation during all phases of facility life cycle.

Manufacturing activities that produce sealed sources should be aware that a common business option is to accept damaged, unwanted, and replaced sources from their customers or salvagers. Sealed sources that may be returned to the facility present an unknown risk to the receiving department staff and to the persons charged with evaluating the condition of received materials.

The manufacturing and distribution applicant may also be requested by customers to provide recovery and shipping services for unwanted, damaged, and replacement sources. As such, the applicants should consider the designs of shipping and receiving containers to meet transportation requirements. Procedures should be developed to enable these activities to be carried out with small impact on the radiological condition of the facility, decommissioning in the future, and employee external and internal radiation exposure.

When submitting new applications, applicants should consider the following:

- Implementation of, and adherence to, good health physics practices in operation;
- Minimization of areas, to the extent practicable, where licensed materials are use and stored;
- Maximization of the frequency of surveys, within reason, to minimize the spread of contamination in the event of a spill;
- Choice of isotope to be used, whenever practical, in consideration of half-life and chemical composition;

- Ventilation stacks and ductwork with minimal lengths and minimal abrupt changes in direction;
- Air flows appropriate to the work being conducted;
- Use of appropriate plumbing materials with minimal pipe-lengths and traps;
- Minimization of the number of disposal sites (sinks) where liquid waste is disposed if there is a sanitary sewer system.

Sealed sources and devices that are approved by the agency, NRC, or another Agreement State and located and used according to their SSD Registration Certificates usually pose little risk of contamination. Leak tests performed as specified in the SSD Registration Certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and decontaminated, repaired, or disposed of according to VDH requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts. Other efforts to minimize radioactive waste do not apply to programs using only sealed sources and devices that have not leaked.

Item 10.12: Waste Management

Rule: 12VAC5-481-100, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-880, 12VAC5-481-900, 12VAC5-481-910, 12VAC5-481-920, 12VAC5-481-930, 12VAC5-481-940, 12VAC5-481-950, 12VAC5-481-960, 12VAC5-481-970, 12VAC5-481-1060, 12VAC5-481-2550, 12VAC5-481-3740

Criteria: Licensed materials must be disposed of in accordance with VDH requirements by transfer to an authorized recipient. Appropriate records must be maintained. Waste licensed materials (such as gloves, rags, tools) may not be received from others. Licensed materials which were distributed (such as decayed sources or devices at the end of their useful life) may be accepted from others, received, and sent for disposal properly.

Discussion: The applicant should discuss the methods of management and disposal of radioactive waste. The program should include procedures for handling of waste, safe and secure storage, waste characterization, waste minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. The applicant should include, where appropriate for the types of waste involved, provisions for monitoring and segregating waste materials (e.g., radioactive from non-radioactive, short from long half-life, liquid from solid waste).

The following methods of waste disposal may be considered and should be addressed in the application as appropriate:

<u>Transfer to an Authorized Recipient</u>
Waste may be transferred to a recipient (usually a waste disposal service company or the original supplier) who is properly licensed to receive such waste in accordance with **12VAC5-481-910.** Each shipment must comply with all applicable regulatory requirements.

Licensees should implement procedures to reduce the volume of radioactive waste for final disposal in an authorized low-level radioactive waste (LLW) disposal facility. These procedures include volume reduction by segregating, consolidating, compacting, or allowing certain waste to decay in storage. Waste compaction or other treatments can reduce the volume of radioactive waste, but such processes may pose additional radiological hazards (e.g., airborne radioactivity) to workers, members of the public, and the environment. Safety procedures to address these concerns should be implemented.

<u>Decay-In-Storage</u>

Storage of radioactive materials with half-lives greater than 120 days should be characterized regarding volume and anticipated time in residence at the licensee's facility prior to disposal. VDH has concluded that materials with half-lives of less than or equal to 120 days are appropriate for decay-in-storage (DIS). The minimum holding period for DIS is ten half-lives of the longest-lived radioisotope in the waste. Care should be taken that the waste form should not degrade or adversely interact with the waste container. Also, care should be taken to group waste packages by half-life. Waste packages having mixed half-lives must be held for 10 half-lives of the longest lived radioisotope in the package. Therefore, waste with a 65 day half-life (held in storage for 650 days), should not be held in the same container for the 1200 days as required for material with a 120 day half-life. Such waste may be disposed of as ordinary trash if radiation surveys (performed in a low background area and without any interposed shielding) of the waste at the end of the holding period indicate that radiation levels are indistinguishable from background. All radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash. If the decayed waste is compacted, all labels that are visible in the compacted mass must also be defaced or removed.

VDH does not consider storage as a substitute for final disposal of radioactive wastes. Other than storage for radioactive decay, LLW should be stored only when disposal capacity is unavailable, and for no longer than is necessary. A model procedure for DIS is contained in **Appendix P**.

Release into Air and Water

The applicant should discuss the monitoring and control mechanisms in place to ensure compliance with the requirements. Applicants are reminded of the "constraint" on air emissions of radioactive material required by **12VAC5-481-630** which effectively reduces the limits specified in **12VAC5-481-730** for release of gaseous effluents by a factor of ten. Applicants considering release of radioactive material into air and water should review NRC's Regulatory Guide 8.37, which deals with the application of ALARA in controlling gaseous and liquid effluents and references documents with acceptable methods of effluent monitoring.

Licensees considering disposal by release to the sanitary sewerage system must comply with the requirements of **12VAC5-481-930.** Licensees are responsible for demonstrating that licensed materials discharged into the sewerage system are readily soluble or biologic readily dispersible in water. NRC IN-94-07 provides the criteria for evaluating solubility of liquid waste. Liquid scintillation media and ash are examples of material that may or may not be readily dispersible. Licensee should carefully consider the possibility of re-concentration of radioisotopes that are released into the sewerage system.

Applicants should provide procedures that will ensure that all releases of radioactive waste into the sanitary sewerage meet the criteria stated in **12VAC5-481-930** and do not exceed the monthly and annual limits specified in the regulations. Licensees are required to maintain accurate records of all releases of licensed material into the sanitary sewerage. A model procedure for disposal of radioactive waste via sanitary sewerage is described in **Appendix P**.

If your facility maintains a private sewerage treatment system, a septic system, or leach fields, the regulations of **12VAC5-481-930** are not applicable for releases to these systems. You may make releases of liquids to private sewerage systems, septic systems, or leach fields as effluents released to unrestricted areas pursuant to **12VAC5-481-730**.

If liquid releases are made to a private sewerage treatment system, septic system or leach field, the sludges or other solids from these systems may become contaminated with radioactive material. Applicants should describe the monitoring planned for these systems in **Item 10.7** of your application. Contaminated sludges will be required to be disposed of as radioactive waste using one of the methods

described in this section. Applicants may obtain approval of alternative disposal methods through application to the agency as described in **12VAC5-481-920**.

Incineration

Applicants who wish to treat or dispose of licensed material by incineration must comply with the requirements of **12VAC5-481-940**. NRC Policy and Guidance Directive PG 8-10 provides guidance relative to the disposal of ash. A model procedure for incineration of licensed material is described in **Appendix P**. Applicants who are considering disposal of radioactive materials by incineration should review NRC Regulatory Guide 8.37 which described the application of ALARA in controlling gaseous and liquid effluents and references documents containing acceptable methods of effluent monitoring.

Waste Volume Reduction

Waste volume reduction operations that could create a radiological hazard to licensee employees or the general public must be described in the application. A model procedure for waste compaction is described in **Appendix P**.

Disposal of Specific Waste as if it were Not Radioactive

The following radioactive waste may be disposed of as non-radioactive waste:

- Liquid scintillation medium containing no more than 1.85 kBq (0.05 μCi) of H-3 or C-14 per gram of the medium;
- Animal carcasses or animal tissue containing no more than 1.85 kBq (0.05 μCi) of H-3 or C-14 per gram averaged over the weight of the entire animal.

Applicants should have procedures that will ensure the above limits are not exceeded and that the disposal of animal tissue or carcasses containing licensed material is in a manner that will not permit their use either as food for humans or animals. Applicants must maintain accurate records of these disposals.

Burial

Licenses will not ordinarily be written to allow this option; however, an applicant can submit a request pursuant to **12VAC5-481-920**.

Other Methods Specifically Approved by VDH Pursuant to **12VAC5-481-920**

Applicants may also request alternative methods for the disposal of radioactive waste generated at their facilities. Such request must describe the waste containing licensed material, including the physical and chemical properties that may be important to assess risks associated with the waste, and the proposed manner and conditions of waste disposal. Additionally, the applicant must submit its analysis and evaluation of pertinent information on the nature of the environment, nature and location of other affected facilities, and procedures to ensure that radiation doses are maintained ALARA and within regulatory limits.

Additional Considerations

The applicant should describe the ALARA considerations taken before disposal of radioactive materials. Discuss the potential for unmonitored or unanticipated release of radioactive materials in work areas and from release points (i.e., hoods and incinerator stacks). To be in compliance with the ALARA philosophy stated in **12VAC5-481-630**, radioactive material waste stream concentrations should be a fraction (generally 10% to 20%) of the limits specified in **Table II** of **12VAC5-481-3740**. Furthermore, due to the variability of inventory control programs for monitoring disposal and releases of radioactive material possessed or in use, a program for physically measuring releases should be put in place whenever releases exceed the specified ALARA action point.

Because of the difficulties and costs associated with disposal of sealed sources, applicants should pre-plan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement. Sealed source manufacturers and suppliers that accept return of sealed sources should consider this when developing their waste management program.

Item 10.13: Termination of Activities

Rule: 12VAC5-481-450 C, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-980, 12VAC5-481-1161

Criteria: The licensee must do the following:

- Notify the agency, in writing, within 60 days of:
  - The expiration of its license;
  - A decision to permanently cease licensed activity at the entire site or in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to VDH requirements;
  - No principal activities have been conducted at the entire site under the license for a period of 24 months;
  - No principal activities have been conducted for a period of 24 months in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to VDH requirements.
- Submit a decommissioning plan, if required by **12VAC5-481-510;**
- Decommissioning, as required by **12VAC5-481-510 & 12VAC5-481-1161;**
- Submit to the agency, a completed VDH form 'Certificate of Disposition of Materials' (**Appendix B**) and demonstrate that the premises are suitable for release for unrestricted use (e.g. results of final survey); and
- Before a license is terminated, send the records important to decommissioning to the agency as required by **12VAC5-481-571**. If licensed activities are transferred or assigned in accordance with **12VAC5-481-500**, transfer records important to decommissioning to the new licensee.

Discussion: For guidance on the disposition of licensed material, see the **Item 10.11 Waste Management**. For guidance on decommissioning records, see the section on **Item 8.2 Radioactive Materials - Financial Assurance and Record Keeping for Decommissioning**.

Licensees must use the VDH Form, 'Certificate of Disposition of Materials' (**Appendix B**) when submitting for termination of a license.

Item 11: License Fees

For a listing of application fees please see **12VAC5-490**. On VDH form, 'Application for a Radioactive Material License Authorizing Manufacturing and Distribution'**,** enter the fee the amount. Enclose fee with the application.

Item 12: Certification

Individuals acting in a private capacity are required to sign and date VDH form, **'**Application for a Radioactive Material License Authorizing Manufacturing and Distribution'. Otherwise, senior representatives of the corporation or legal entity filing the application should sign and date VDH form, 'Application for a Radioactive Material License Authorizing Manufacturing and Distribution'. **Representatives signing an application must be authorized to make binding commitments and sign official documents on behalf of the applicant**. The agency will return all unsigned applications for proper signature**.**

Note:

- It is a violation of **12VAC5-481-30** to make a willful false statement or representation on applications or correspondence.
- When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

Appendix A:

VDH Form,
Application for a Radioactive Material License Authorizing Manufacturing and Distribution

The Form is located at:
http://www.vdh.state.va.us/epidemiology/radiologicalhealth/Materials/

Attachment A
Manufacturing & Distribution Applicant's Checklist

Yes	No	Item	Material Needed
		Application	Used the correct form (New for new licensees or Renewal for renewing licensees)
		Application	Checked at least one box and filled in all the required information, as needed, for all Items
		Item 4	Completely included all information and provided additional sheet, as appropriate, on field locations
		Item 5	Checked box or attached alternate procedure
		Item 7	Checked box(es) and attached radiation safety program descripted
		Item 8	Completely included all information and, as necessary, attached supplemental sheets
		Item 9	Checked box(es) and attached facility description and diagram
		Item 10.2	Checked box(es) or attached alternate procedures
		Item 10.3	Checked box(es) and attached procedures
		Item 10.6	Checked box(es) or attached alternate procedures
		Item 10.6.1	Checked box(es) and attached license verification procedure
		Item 10.7	Checked box(es) or attached alternate procedures
		Item 10.8	Checked box(es) or attached alternate procedures
		Item 10.9	Checked box(es) and attached maintenance procedure
		Item 10.12	Checked box(es) or attached alternate procedures

Appendix B:

VDH Form
‘Certificate of Disposition of Materials’

Virginia Department of Health
Radioactive Materials Program
(804) 864-8150

CERTIFICATE OF DISPOSITION OF MATERIALS

Completion of this form is required to complete termination of a Radioactive Material License as outlined in **12VAC5-481-500**. Failure to provide information will result in this request for termination of a specific license not being processed.

Instructions – Complete all items. Retain one copy and submit original to Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219.

CONTACT INFORMATION

Item 1 Name and Mailing Address of Applicant:	**Item 2 Virginia Radioactive Material License Number**
	Item 3 Contact Person – Name
	Contact Person - Telephone Number (Include area code) ( ) - x

TERMINATION AND DISPOSITION INFORMATION

The following information is provided in accordance with **12VAC5-481-510.** (Check all that apply)

☐ **Item 4** All use of radioactive material authorized under the above referenced license has been terminated.

☐ **Item 5** Radioactive contamination has been removed to the levels outlined in **12VAC5-481-1161 B.**

☐ **Item 6** All radioactive material previously procured and/or possessed under the authorization granted by the above referenced license has been disposed of as follows. (Check all that apply)

☐ Transferred to: Name Address

Who is (are) authorized to possess such material under Licensed Number:

Issued by (Licensing Agency):

☐ Decayed, surveyed and disposed of as non-radioactive waste.

☐ No radioactive material has ever been procured and/or possessed by the licensee under the authorization granted by the above referenced license.

☐ Other (Attach additional pages)

☐ **Item 7** Attached are radiation surveys or equivalent as specified in **12VAC5-481-510 L**. Specify the survey instrument(s) used and certify that each instrument is properly calibrated as required in **12VAC5-481-510 K**.

☐ **Item 8** Records required to be maintained for the license termination requested are available at the following location(s):
Name:

Address:

Contact Person Telephone Number: ( ) - x

Additional remarks (Attach additional pages if necessary.)

CERTIFICATION (To be completed by an individual authorized to make binding commitments on behalf of the applicant.)

Item 10.

The undersigned, on behalf of the licensee, hereby certifies that licensable quantities of radioactive material under the jurisdiction of the Virginia Department of Health are not possessed by the licensee. It is therefore requested that the above referenced radioactive material license be terminated.

SIGNATURE - Applicant or Authorized Individual	**Date signed**

Print Name and Title of above signatory

Appendix C:

Information Needed for Transfer of Control Application

Information Needed for Transfer of Control Application

Control: Control of a license is in the hands of the person or persons who are empowered to decide when and how that license will be used. That control is to be found in the person or persons who, because of ownership or authority explicitly delegated by the owners, possess the power to determine corporate policy, and thus the direction of the activities under the license.

Transferee: A transferee is an entity that proposes to purchase or otherwise gain control of a VDH licensed operation.

Transferor: A transferor is a VDH licensee selling or otherwise giving up control of a licensed operation.

Licensees must provide full information and obtain VDH's **prior written consent** before transferring control of the license. Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

1. Provide a complete description of the transaction (transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact who the agency may contact if more information is needed.

2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.

3. Describe any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.

4. Describe the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.

5. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to VDH, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.

6. Confirm that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

Appendix D:

Radiation Safety Officer Duties and Responsibilities and Sample Delegation of Authority

Radiation Safety Officer Duties and Responsibilities

The RSO's duties and responsibilities include ensuring radiological safety and compliance with VDH and DOT regulations and the conditions of the license. Typically, these duties and responsibilities include the following:

- Ensure that licensed material possessed by the licensee is limited to the types and quantities of radioactive material listed on the license.
- Maintain documentation that demonstrates that the dose to individual members of the public does not exceed the limit specified in **12VAC5-481-720**.
- Ensure security of radioactive material.
- Posting of documents as required by **12VAC5-481-860**.
- Ensure that licensed material is transported in accordance with applicable VDH and DOT requirements.
- Ensure that radiation exposures are "ALARA."
- Oversee all activities involving radioactive material, including monitoring and surveys of all areas in which radioactive material is used.
- Act as liaison with VDH and other regulatory authorities.
- Provide necessary information on all aspects of radiation protection to personnel at all levels of responsibility, pursuant to **12VAC5-481 'Virginia Radiation Protection Regulations'**.
- Oversee proper delivery, receipt, and conduct of radiation surveys for all shipments of radioactive material arriving at or leaving from the institution, as well as packaging and labeling all radioactive material leaving the institution.
- Determine the need for personnel monitoring, distribute and collect personnel radiation monitoring devices, evaluate bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching the limits, and recommend appropriate remedial action.
- Conduct training programs and otherwise instruct personnel in the proper procedures for handling radioactive material prior to use, at periodic intervals (refresher training), and as required by changes in procedures, equipment, rules, etc.
- Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and record keeping on waste storage and disposal records.
- Oversee the storage of radioactive material not in current use, including waste.
- Perform or arrange for leak tests on all sealed sources and calibration of radiation survey instruments.
- Maintain an inventory of all radioisotopes possessed under the license and limit the quantity to the amounts authorized by the license.
- Immediately terminate any unsafe condition or activity that is found to be a threat to public health and safety or property.
- Supervise decontamination and recovery operations.
- Maintain other records not specifically designated above, for example, records of receipts, transfers, and surveys as required by **12VAC5-481-100, 12VAC5-481-571, 12VAC5-481-980** and **12VAC5-481-1000**.
- Hold periodic meetings with, and provide reports to, licensee management.
- Ensure that all users are properly trained.

- Perform annual audits of the radiation safety program to ensure that the licensee is complying with all applicable VDH requirements and the terms and conditions of the license (e.g., leak tests, inventories, use limited to trained, approved users, etc.), the content and implementation of the radiation safety program to achieve occupational doses and doses to members of the public that are "ALARA" in accordance with **12VAC5-481-630** and required records are maintained.
- Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented (and maintained for at least 3 years) and provided to management for review; ensure that prompt action is taken to correct deficiencies.
- Ensure that the audit results and corrective actions are communicated to all personnel who use licensed material.
- Ensure that all incidents, accidents, and personnel exposure to radiation in excess of "ALARA" or **12VAC5-481-630, 12VAC5-481-640** and **12VAC5-481-720** limits are investigated and reported to VDH and other appropriate authorities, if required, within the required time limits.
- Maintain understanding of and up-to-date copies of **12VAC5-481 'Virginia Radiation Protection Regulations'**, the license, revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to VDH during the licensing process.

Model Delegation of Authority

Memo To: Radiation Safety Officer
From: Chief Executive Officer
Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with the rule. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Virginia Department of Health at anytime. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

_____
Signature of Management Representative

I accept the above responsibilities,

_____
Signature of Radiation Safety Officer

cc: Affected department heads.

Model Correspondence Delegation

[date]

Virginia Department of Health
Radioactive Materials Program
109 Governor Street, Room 730
Richmond, Virginia 23219

To Radioactive Material Program:

As [job title] of [name of licensee], I have delegated authority for all matters pertaining to our Radioactive Material License to [name of designee]. [Name of designee] has management approval to sign and submit amendment requests to the Virginia Department of Health on behalf of [name of licensee]. I understand that license renewals must still be signed by a representative of upper management.

[This document must be signed by a management representative who has independent authority to reassign job duties and/or provide finances, if necessary, to support an effective radiation safety program.]

_____ _____ _____

Signature Title Date

_____

Print Name

Appendix E:

Radiation Safety Training

Criteria for Acceptable Training for Authorized Users and Radiation Safety Officers

This appendix is intended only as a guide for developing a training program. Individuals working with radioisotopes may not require training on every topic provided. For example, housekeeping staff may need to know only what symbols to look for, which waste cans to empty, or which areas to enter or avoid. Conversely, laboratory technicians may require detailed information on particular topics. As a result, instruction for some individuals may be provided by providing a simple hand-out, whereas others may require extensive training, including a written exam to assess retention of the topics presented.

Frequency of Training

A. Before assuming duties with, or in the vicinity of, radioactive materials
B. Whenever there is a significant change in duties, VDH rule, or the terms of the license
C. Annually (refresher training)

General Information

A. Radiation safety
    1. radiation vs. contamination
    2. internal vs. external exposure
    3. biological effects of radiation
    4. ALARA concept
    5. use of time, distance, and shielding to minimize exposure
    6. contact dose rates and dose rates at a distance from high activity sources
    7. dose reduction responsibilities

B. Regulatory requirements
    1. RSO
    2. material control and accountability
    3. personnel dosimetry
    4. radiation safety program audits
    5. transfer and disposal
    6. record keeping
    7. surveys
    8. postings
    9. labeling of containers
    10. handling and reporting of incidents or events
    11. licensing and inspection by VDH
    12. need for complete and accurate information
    13. employee protection
    14. deliberate misconduct.

Licensee-Specific Program Elements

A. Authorized users and supervised users
B. Worker-specific manufacturing process tasks
C. Shipping
D. Ordering and receiving radioisotopes

E. Applicable VDH requirements and license conditions
F. Areas where radioactive material is used or stored
G. Potential hazards associated with radioactive material in each area where the individuals will work
H. Appropriate radiation safety procedures
I. Licensee's in-house work rules. (For instructions on laboratory safety and uses of radioisotopes, see **Appendix M** and 'For Facility Safety and Use of Radioisotopes' below.)
J. Each individual's obligation to report unsafe conditions to the RSO
K. Appropriate response to spills, emergencies or other unsafe conditions
L. Worker's right to be informed of occupational radiation exposure and bioassay results, if applicable
M. Locations where the licensee has posted or made available: notices, copies of pertinent VDH rule, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by **12VAC5-481-2260**.
N. Emergency procedures:
    1. RSO name and telephone number
    2. immediate steps to prevent or control spread of contamination
    3. clean-up instructions, decontamination.
O. Survey program:
    1. survey instrument accessibility
    2. who is responsible
    3. types, contamination and area
    4. frequency
    5. levels of contamination
    6. personnel, hands, shoes
    7. records
P. Waste
    1. liquid
    2. solids
    3. sanitary sewer
    4. burial (transfer to low level waste repository)
    5. storage
    6. decay-in-storage
    7. waste storage surveys
    8. incineration
    9. records
Q. Dosimetry
    1. whole body
    2. extremities
    3. lost or replacement badges and dose assessment
    4. bioassay procedures
    5. records
R. Instrumentation
    1. survey meters-use, calibration frequency, use of check sources
    2. analytical instruments-gas chromatographs, liquid scintillation counters
S. Procedures for receiving packages containing radioactive materials
    1. normal
    2. off-duty
    3. notification of user and RSO
    4. security
    5. exposure levels
    6. possession limit
    7. receipt of damaged packages

T. Procedures for opening and examining packages
    1. leakage and contamination
    2. monitoring packages
    3. monitoring packing materials
    4. gloves
    5. transferring material to users
U. Animal experiments
    1. description of facilities
    2. safety instructions, including handling of animals, waste, carcasses, and cleaning and decontamination of cages
    3. security
V. Sealed sources
    1. leak test requirements
    2. inventory requirements
    3. exempt quantities
    4. records
W. VDH and licensee audit findings
X. Other topics, as applicable
Y. Question and answer period

For Facility Safety and Use of Radioisotopes

A. Control procedures for obtaining permission to use radioactive materials at the facility; give limitations on quantity to be handled per user, allowed per device, etc.
B. Protective clothing and what protective apparel to wear and what equipment to use.
C. Limitations and conditions relative to handling unsealed licensed material and what equipment to use when working with such material. As an example, discuss which licensed materials and what procedures should be confined to radiochemical fume hoods or gloveboxes. Explain what shielding or remote handling equipment is to be used when beta and/or gamma emitting licensed materials are handled.
D. Routine survey and monitoring procedures to be followed for contamination control. Include where and how contaminated articles and glassware are to be handled and stored.
E. Emergency procedures concerning spills, fires, release of material, and/or accidental contamination of personnel.
F. Decontamination procedures to use and whom to contact in case of an emergency.
G. Instructions concerning transfer of licensed materials between rooms, halls, or corridors, if applicable.
H. Requirements for storage, labeling of containers, and identification of areas where licensed materials are used.
I. Personnel monitoring devices to use, where to obtain them, and exchange procedures and exposure results.
J. Waste disposal procedures to follow limitations for disposal of liquid or solid wastes, and procedures to use for waste storage. If program involves animals, procedures for cleaning animal quarters and handling animal excreta and carcasses for disposal.
K. Records to be maintained on use and disposal of licensed materials.
L. Prohibition of pipetting by mouth, eating, smoking, and drinking in areas where licensed materials are used.

Appendix F:

Facilities and Equipment

Facilities and Equipment Considerations

Below is a list of topics that should be considered when developing a description of the facilities and equipment that a manufacturing and distribution licensee will use or otherwise have available. Not every manufacturing and distribution applicant will need to address each topic in its application.

- Restricted areas are defined as areas to which access is limited by the licensee to protect individuals against undue risks from exposure to radiation and radioactive materials. The application should contain detailed descriptions and diagrams of the facilities, including information about the shielding properties of the construction materials used. Scaled drawings and sketches should be submitted showing the relationship between restricted areas and unrestricted areas and the location of all pertinent safety-related equipment. Drawings should show the use of adjacent areas, including those beside, above, and below.
- A site diagram should indicate buildings and areas and their uses such as assembly, production, or waste storage.
- Bench top or open work areas may be used for sealed sources, for small quantities of solid materials in a form not likely to become airborne or dispersed, and for small quantities of liquids of such low volatility as not to cause airborne contamination or toxicity problems. Trays and/or absorbent surface covers to catch and retain spilled liquids should be used on these open work surfaces and inside closed systems discussed below. Surfaces should be smooth and non-porous, to facilitate decontamination.
- Radioactive materials that are handled or used in unsealed forms should be confined to control the release of material and to prevent the spread of contamination. Gaseous, volatile, and fine particulate solid materials should be handled in closed or isolated systems such as fume hoods or glove boxes with controlled, and possibly filtered, exhaust systems.

  Chemical-type fume hoods provide a working area with controlled inward airflow from the room to the hood exhaust system. Hoods are used for gases, for unsealed volatile licensed materials, and for processes such as evaporation that may release gases and vapors. Fume hoods provide emergency ventilation and exhaust for unplanned releases, such as accidental spills and ruptures, as well as routine exhaust of effluents. Filters may be required in the exhaust stream unless monitoring and/or calculations demonstrate that any planned or likely effluent will be in accordance with the limits found in **12VAC5-481-3690**. Glove boxes are sealed boxes with transparent viewing windows, seal-able ports or doors for transferring materials and equipment, and gloves sealed to the box through which licensed materials are handled. Glove boxes are used for the containment during storage and use of liquids and solids that can become airborne particulates or aerosols. Glove boxes can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.
- Sink faucets should be designed, where possible, for operation by foot, knee, or elbow rather than by hand.
- Plumbing and ductwork should be designed to avoid radioactive contamination build-up. This build-up of contamination can create external radiation exposure hazards and problems for decommissioning.
- Shielding consisting of lead or other high-density material in the form of bricks, panels, L-shields, storage containers, or other shapes may be used on bench tops, in fume hoods or in glove boxes to reduce radiation exposure from gamma-emitting radioactive materials. Similarly, shielding of low atomic number material, such as high-density plastic, may be used to reduce the exposure from high-energy beta-emitting materials. Shielded shipping containers are frequently used for continued storage after receipt of materials.

- Optimal shielding requirements will depend on the intensity and energy of the beta radiation; the type, quality, and configuration of local shielding in place; and the duration of personnel exposure in conducting the operation with a high-energy beta emitting radionuclide. In operations using large quantities of high energy beta emitting radionuclides and/or longer exposure times, it may be necessary to also reduce the bremsstrahlung by adding shielding containing high-atomic number material such as lead. These shields generally are low-atomic number materials closest to the source, enclosed by high atomic number material.
- A particular sink should be designated for disposal of liquid radioactive waste to the sanitary sewerage system. In some cases, depending on number of users and distance between areas of use, more than one sink may need to be designated.
- Labeled waste containers should be used. These containers may be shielded as necessary, placed near the waste generating areas and away from areas frequently occupied by personnel. Additionally, these containers should be effectively enclosed to prevent airborne contamination from radioactive materials deposited.
- Remote handling tools, such as forceps or extension handles, should be used to provide distance in the handling of radioactive materials (ALARA). In addition, shielded handling devices, such as shielded syringes, can be used to protect workers from materials that cannot be handled remotely. Pipetting should be done using appropriate devices. Pipetting by mouth should be strictly forbidden.
- Where appropriate, ventilation systems should be designed such that, in the event of an accident, they can be shut down to prevent the spread of radioactivity.
- Designated areas should be provided, for coats and personal belongings, to avoid contamination.
- Areas with background radiation levels should be designated for personnel dosimetry storage when not in use.
- Areas of use should be well lighted to avoid spills and other accidents that could result in contamination build-up.
- Observation of activities conducted behind shielding with remote tools (or with extended arms and hands, within limits consistent with permissible occupational exposures) can be accomplished by mirrors, through shielded (e.g., leaded glass) windows, through transparent plastic beta shields, or by remote video monitoring.
- The combination of containment, shielding, and handling devices proposed for any use of radioactive materials should be appropriate to the type and quantity of materials to be used and to the type and duration of operations to be conducted.
- If respiratory protective equipment will be used to limit inhalation of airborne licensed material, follow the provisions of **12VAC5-481-830.**
- If compaction of waste is performed, ensure that facilities are adequate for the ventilation of the area where the waste is compacted. In addition, also ensure that air sampling for internal exposures is available, if needed per **12VAC5-481-670.**

Appendix G:

Sample Audit Form

Suggested Annual Radiation Protection Program Audit

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit. For example, licensees do not need to address areas that do not apply to the licensee's activities, and activities that have not occurred since the last audit need not be reviewed at the next audit.

Date of This Audit:_____ Date of Last Audit: _____

Next Audit Date:_____

Auditor: _____ Date: _____
(Signature)

Management Review: _____ Date: _____
(Signature)

Audit History

A. Were previous audits conducted annually (**12VAC5-481-630)**?

B. Are records of previous audits being maintained for three years after they were made (**12VAC5-481-990)**?

C. Were any deficiencies identified during previous audit?

D. Were corrective actions taken? (**Note:** Look for repeated deficiencies.)

Amendments Since Last Audit:

A. Any amendments since last inspection (**12VAC5-481-530**)?

Notifications Since Last Audit:

A. Any notifications since last audit?

Organization and Scope of Program

A. Radiation Safety Officer:

1. If the RSO position has changed, was license amended (**12VAC5-481-450)**?
2. Does the new RSO meet the agency's training requirements (**12VAC5-481-450**)?
3. Is the RSO fulfilling all of his/her duties?
4. Is the written agreement in place for new RSO?

B. Multiple places of radioactive material use? If yes, list all locations of use.

C. Are all locations of use listed on the license?

D. Were annual audits performed at each location (**12VAC5-481-630*)***? If no, explain.

E. Describe scope of the program (staff size, number of production lines, different processes, etc.).

F. Licensed Material:

1. The isotope, the chemical forms, the quantity and authorized use is listed (**L/C**)**.**
2. Does the total amount of radioactive material possessed require financial assurance? If so, is financial assurance adequate? (**12VAC5-481-450 C)**

G. Are the sealed sources possessed and used as described in the Sealed Source and Device Registration (SSDR) Certificate (**12VAC5-481-440, 12VAC5-481-450,** and **12VAC5-481-480**)? Are copies of (or access to) SSDR Certificates possessed? Are manufacturers' manuals for operation and maintenance of medical devices possessed?

H. If places of use changed, was the license amended (**12VAC5-481-450)**?

I. If control of the license was transferred or bankruptcy filed, was the agency's prior consent obtained or notification made, respectively (**12VAC5-481-500)**?

Radiation Safety Program

A. Minor changes or revision to radiation safety program?

B. Records of changes maintained for 5 years?

C. Content and implementation reviewed annually by the licensee (**12VAC5-481-630)**?

D. Records of annual reviews maintained 3 years after the date on which they were made (**12VAC5-481-990)**?

Training, Retraining, And Instructions to Workers

A. Have workers been provided with all required instructions (**12VAC5-481-2270)**?

B. Is the individual worker understanding of current procedures and VDH rules adequate?

C. Training program implemented?

1. Awareness of operating procedures and emergency procedures?
2. Were all workers who are likely to exceed 1.0 mSv (100 mrem) in a year instructed, and was refresher training provided (**12VAC5-481-2270)**?
3. Was each supervised user instructed in the licensee's written radiation protection procedures, as appropriate?
4. Are initial and periodic training records maintained for each individual for three years (**12VAC5-481-100)**?
5. Briefly describe training program:

D. Workers cognizant of requirements for:
1. Radiation Safety Program (**12VAC5-481-630, 12VAC5-481-2270)**?
2. Annual dose limits (**12VAC5-481-640, 12VAC5-481-700, 12VAC5-481-710, 12VAC5-481-720**]?
3. VDH Form, 'Occupational Exposure Record Per Monitoring Period'
4. 10% monitoring threshold (**12VAC5-481-760)**?

5. Dose limits to embryo/fetus and declared pregnant worker (**12VAC5-481-710)**?
6. Extreme Danger/Grave Danger Posting (**12VAC5-481-860)**?
7. Procedures for opening packages (**12VAC5-481-900, 12VAC5-481-3091)**?

Facilities

A. Facilities as described in license application (**L/C**)?

B. Storage areas:

1. Materials secured from unauthorized removal or access (**12VAC5-481-840)**?
2. Licensee controls and maintains constant surveillance of licensed material not in-storage (**12VAC5-481-840)**?

Radiation Protection and Control of Radioactive Material

A. Use of licensed material:

1. Protective clothing worn?
2. Personnel routinely monitor their hands?
3. No eating/drinking in use/storage areas?
4. No food, drink, or personal effects kept in use/storage areas?
5. Proper dosimetry worn?
6. Radioactive waste disposed of in proper receptacles?
7. Appropriate shielding and extension tools utilized, when appropriate?

B. Leak tests and Inventories:

1. Leak test performed on sealed sources (**12VAC5-481-740)**?
2. Inventory of sealed sources performed semi-annually (**L/C)**?
3. Records maintained for three years (**12VAC5-481-100)**?

Radiation Survey Instruments

A. Survey instruments used to show compliance with **12VAC5-481-450 A** and **12VAC5-481**, 'Virginia Radiation Protection Regulations', **Part IV** 'Standards for Protection Against Radiation':

1. Appropriate operable survey instruments possessed or available (**12VAC5-481-450)**
2. Calibrations (**12VAC5-481-750)**:
3. Records maintained for three years (**12VAC5-481-1000)**?

B. Radiation surveys performed in accordance with the licensee's procedures and the regulatory requirements (**12VAC5-481-750)**?

1. Daily in all areas where unsealed licensed material is used?
2. Weekly in all areas where licensed material or waste is stored?
3. Weekly wipes in all areas where licensed material is processed and/or stored?
4. Trigger levels established?
5. Corrective action taken and documented if trigger level exceeded?

6. Surveys made to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the sources(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry and records maintained?
7. Air sampling conducted, as needed (**12VAC5-481-830**)?

Public Dose

A. Is licensed material used in a manner to keep doses below 1 mSv (100 mrem) in a year (**12VAC5-481-720)**?

B. Has a survey or evaluation been performed per **12VAC5-481-730**?

C. Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?

D. Do unrestricted area radiation levels exceed 0.02 mSv (2 mrem) in any one hour (**12VAC5-481-720)**?

E. Is licensed material used or stored in a manner that would prevent unauthorized access or removal (**12VAC5-481-840)**?

F. Records maintained (**12VAC5-481-1050)**?

Radioactive Waste

A. Disposal:

1. Decay-in-storage (**L/C**)?
2. Procedures followed?
3. Labels removed or defaced (**12VAC5-481-880)**?

B. Special procedures performed as required (**L/C)**?

C. Improper/unauthorized disposals (**12VAC5-481-910)**?

D. Records maintained (**12VAC5-481-100, 12VAC5-481-571, 12VAC5-481-1000, 12VAC5-481-1060**)?

E. Effluents:

1. Release to sanitary sewer (**12VAC5-481-930)**?
    a. Material is readily soluble or readily dispersible (**12VAC5-481-930)**?
    b. Monthly average release concentrations do not exceed **12VAC5-481-3690, Table III** values?
    c. No more than 185 GBq (5.0 Ci) of H-3, 37GBq (1.0 Ci) of C-14 and 37 GBq (1.0 Ci) of all other radionuclides combined released in a year (**12VAC5-481-930)**?
    d. Procedures to ensure representative sampling and analysis implemented (**12VAC5-481-630)**?
2. Release to septic tanks (**12VAC5-481-930)**?

a. Within unrestricted limits **12VAC5-481-3690, Table III** and **12VAC5-481** 'Virginia Radiation Protection Regulations'**, Part IV** 'Standards for Protection Against Radiation'?

3. Waste incinerated?
    a. License authorizes (**12VAC5-481-940)**?
    b. Directly monitor exhaust?
    c. Airborne releases evaluated and controlled (**12VAC5-481-730, 12VAC5-481-750)**?
4. Air effluents and ashes controlled (**12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-750, 12VAC5-481-910)**?
    a. Air effluent less than 10 mrem constraint limit (**12VAC5-481-630)**?
    b. If no, reported appropriate information to VDH.
        i. Corrective actions implemented and on schedule?
    c. Description of effluent program:
        i. Monitoring system hardware adequate?
        ii. Equipment calibrated, as appropriate?
        iii. Air samples/sampling technique (i.e., charcoal, HEPA, etc.) analyzed with appropriate instrumentation?

F. Waste storage:

1. Protection from elements and fire?
2. Control of waste maintained (**12VAC5-481-840)**?
3. Containers properly labeled and area properly posted (**12VAC5-481-860, 12VAC5-481-880)**?
4. Package integrity adequately maintained?

G. Waste disposal:

1. Sources transferred to authorized individuals (**12VAC5-481-570, 12VAC5-481-910)**?
2. Name of organization: _____.

H. Records of surveys and material accountability are maintained (**12VAC5-481-1000, 12VAC5-481-1060)**?

Receipt and Transfer of Radioactive Material

A. Describe how packages are received and by whom.

B. Written package opening procedures established and followed (**12VAC5-481-900. 12VAC5-481-3091)**?

C. All incoming packages with a DOT label monitored for radioactive contamination, unless exempted (gases and special form) [**12VAC5-481-900**]?

D. Incoming packages surveyed (**12VAC5-481-900)**?

E. Monitoring in (C) and (D) performed within time specified (**12VAC5-481-900)**?

F. Transfer(s) performed per **12VAC5-481-570**?

G. All sources surveyed before shipment and transfer (**12VAC5-481-750, 49 CFR 173.475(i))**?

H. Records of surveys and receipt/transfer maintained (**12VAC5-481-100, 12VAC5-481-571, 12VAC5-481-1000)**?

I. Package receipt/distribution activities evaluated for compliance with **12VAC5-481-720**?

Transportation [12VAC5-481-2980 and 49 CFR 171-189]

A. Shipments are:

1. Delivered to common carriers;
2. Transported in own private vehicle;
3. Both;
4. No shipments since last audit.

B. Packages:

1. Authorized packages used?
2. Performance test records on file?
    a. DOT-7A packages
    b. Special form sources
3. Two labels (White-I, Yellow-II, or Yellow-III) with TI, Nuclide, Activity, and Hazard Class?
4. Properly marked (Shipping Name, UN Number, Package Type, RQ, "*This End Up*" (liquids), Name and Address of consignee)?
5. Closed and sealed during transport?

C. Shipping Papers:

1. Prepared and used?
2. Proper Shipping Name, Hazard Class, UN Number, Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, Category of Label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, "*Limited Quantity*" (if applicable), "*Cargo Aircraft Only*" (if applicable)?
3. Readily accessible during transport?

Personnel Radiation Protection

A. Exposure evaluation performed (**12VAC5-481-750)**?

B. ALARA program implemented (**12VAC5-481-630)**?

C. External Dosimetry

1. Monitor workers per **12VAC5-481-760**?
2. External exposures account for contributions from airborne activity (**12VAC5-481-660)**?
3. Dosimetry supplier _____ Exchange frequency _____.
4. Supplier is NVLAP-approved (**12VAC5-481-750)**?
5. Dosimeter frequency exchanged as recommended by the supplier.

D. Internal Dosimetry:

1. Monitor workers per **12VAC5-481-760**?
2. Briefly describe program for monitoring and controlling internal exposures (**12VAC5-481-810, 12VAC5-481-820)**?
3. Monitoring/control program implemented (includes bioassays)?
4. Respiratory protection equipment (**12VAC5-481-830)**?

E. Review of Records and Reports:

1. Reviewed by _____ Frequency _____
2. Auditor reviewed personnel monitoring records for period _____ to _____
3. Prior dose determined for individuals likely to receive doses (**12VAC5-481-680)**?
4. Maximum exposures TEDE: _____ Other: _____
5. Maximum CDEs: _____ Organ(s): _____
6. Maximum CEDE: _____
7. Internal and external summed (**12VAC5-481-650)**?
8. Were occupational limits met (**12VAC5-481-640)**?
9. VDH forms or equivalent used (**12VAC5-481-1020, 12VAC5-481-1030, 12VAC5-481-1040)**?
   a. VDH Form, 'Occupational Exposure Record Per Monitoring Period'
10. If a worker declared her pregnancy in writing during audit period, then was the dose in compliance (**12VAC5-481-710)** and were the records maintained (**12VAC5-481-1040)**?
11. Were annual occupational exposure reports provided to workers (**12VAC5-481-2280**)?

F. Who performed any planned special exposures at this facility (number of people involved and doses received) [**12VAC5-481-680, 12VAC5-481-690, 12VAC5-481-1030, 12VAC5-481-1120**]?

G. Records of exposures, surveys, monitoring, and evaluations maintained (**12VAC5-481-990, 12VAC5-481-1000, 12VAC5-481-1040)**?

Confirmatory Measurements

Detail location and results of confirmatory measurements.

Notification and Reports

A. In compliance with **12VAC5-481-1090**, **12VAC5-481-1100**, **12VAC5-481-1110**, **12VAC5-481-1150**, and **12VAC5-481-2280** (reports to individuals; public and occupational doses monitored to show compliance with **12VAC5-481** 'Virginia Radiation Protection Regulations', **Part IV** 'Standards for Protection Against Radiation')?

B. In compliance with **12VAC5-481-1090** (theft or loss)?

C. In compliance with **12VAC5-481-1100** and/or **12VAC5-481-1100** (incidents)?

D. In compliance with **12VAC5-481-1100** and/or **12VAC5-481-1110** (overexposures and high radiation levels)?

E. Aware of the Radioactive Materials Program phone numbers [Office: (804) 864-8150, 24-hour: (800) 468-8892]

F. In compliance with **12VAC5-481-1110** (constraint on air emissions)?

Posting and Labeling

A. VDH Form, 'Notice to Employees' is posted (**12VAC5-481-2260)**?

B. **12VAC5-481** 'Virginia Radiation Protection Regulations'**, Part IV** 'Standards for Protection Against Radiation' and **Part X** 'Notices, Instructions and Reports to Workers', license documents, operating procedures applicable to activities under the license or registration are posted or post a notice indicating where documents may be examined. (**12VAC5-481-2260)**?

C. Other posting and labeling per **12VAC5-481-850, 12VAC5-481-860** and/or **12VAC5-481-880** and not exempted by **12VAC5-481-870** or **12VAC5-481-890**?

Source or Device Review

A. Device registration documents available and followed? If submitting for approval, all appropriate tests completed, results recorded, and forwarded for review to NRC or another agreement state?

B. Maintenance of a quality assurance/control program as specified in rule?

C. Any changes to quality program or devices?

Recordkeeping for Decommissioning

A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination (**12VAC5-481-450 C**)?

B. Records include all information outlined in **12VAC5-481-450 C**?

Information Notices and Regulatory Issue Summaries

A. VDH Information Notices, etc., received?

B. Appropriate action in response to VDH Information Notices, etc.?

Special License Conditions or Issues

A. Special license conditions or issues to be reviewed:

B. Evaluation:

Evaluation of Other Factors

A. RSO has management support for all matters related to radiation safety?

Audits and Findings

A. Summary of findings:

B. Corrective and preventive actions of those measurements) as required by **12VAC5-481-1000**.

Attachment A
Radioactive Drug Distributors

1. Indicate type of operation:

   A. Registered or licensed with U. S. Food and Drug Administration as a drug manufacturer…….. ☐

   B. Registered or licensed with State Agency as a drug manufacturer…… ☐

2. Periodically reviews work of supervised individuals preparing drugs, and records kept to reflect work (**L/C**)……..……. ☐ YES ☐ NO

   Basis for Findings:

3. Radioactive drugs are measured (assayed) by direct measurement or combination of measurement and calculation before commercial distribution (**12VAC5-481-480 I**)……. ☐ YES ☐ NO

   Basis for Findings:

4. Instrumentation Used to Measure Radioactivity of Drugs

   A. List types of equipment used to assay alpha and beta particles.

   B. Procedures for instrument use develop and implemented (**12VAC5-481-480 I**).. ☐ YES ☐ NO

   C. Calibration test performed before initial use, periodically, and following repair? Accuracy, linearity, and geometry dependence performed as appropriate for use of the instrument (**12VAC5-481-480 I; L/C**)…… ☐ YES ☐ NO

   D. Adjustment to instrumentation made when necessary (**12VAC5-481-480 I**)…… ☐ YES ☐ NO

   E. Instruments are checked for constancy and proper operation at the beginning of each day of use (**12VAC5-481-480 I; L/C**)……. ☐ YES ☐ NO

   Basis for Findings:

5. Transport radiation shield (on transfers for distribution) labeled with radiation symbol, "CAUTION RADIOATIVE MATERIAL", name, and quantity at specified date and time (**12VAC5-481-480 I; L/C**)…… ☐ YES ☐ NO

Note: The time may be omitted for drugs with a half-life greater than 100 days.

6. Syringes, vials, or other containers labeled with radiation symbol, "CAUTION RADIOACTIVE MATERIAL", and an identifier to correlate with the information on the transport radiation shield label (**12VAC5-481-480 I; L/C**)…….. ☐ YES ☐ NO

Basis for Findings:

Appendix H:

Radiation Monitoring Instrument Specifications and Model Survey Instrument and Air Sampler Program

Radiation Monitoring Instrument Specifications, Survey Instrument and Air Sampler Calibration Program

Radiation Monitoring Instrument Specifications

The specifications in **Table 7** will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facilities.

Table 7: Typical Survey Instruments[1]
(Instruments used to measure radiological conditions at licensed facilities.)

Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	**Radiation**	**Energy Range**	**Efficiency**
REM Meter	Neutron	mrem - rem	Low
Exposure Rate Meters	Gamma, X-Ray	μR-R	N/A
Count Rate Meters			
Zinc Sulfide	Alpha	All energies (dependent on window thickness)	Moderate
GM	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Gas Flow Proportional	Alpha	All energies	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate
Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detectors	**Radiation**	**Energy Range**	**Efficiency**
LSC*	Alpha	All energies	High
	Beta	All energies	High
	Gamma		Moderate
Gamma Counter (NaI)*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

[1] Table from The Health Physics & Radiological Health Handbook, Revised Edition, Edited by Bernard Shleien, 1992 (except for * items).

Instrument Calibration Program

Training

Before allowing an individual to perform survey instrument calibrations, the RSO will ensure that he or she has sufficient training and experience to perform independent survey instrument calibrations.

Classroom training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection;
- Radioactivity measurements, monitoring techniques, and using instruments;
- Mathematics and calculations basic to using and measuring radioactivity; and
- Biological effects of radiation.

Appropriate on-the-job-training consists of the following:

- Observing authorized personnel performing survey instrument calibration; and
- Conducting survey meter calibrations under the supervision and in the physical presence of an individual authorized to perform calibrations.

Facilities and Equipment for Calibration of Dose Rate or Exposure Rate Instruments

- To reduce doses received by individuals not calibrating instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present.
- Individuals conducting calibrations will wear assigned dosimetry.
- Individuals conducting calibrations will use a calibrated and operable survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Procedure for Calibrating Survey Instruments

A radioactive sealed source(s) used for calibrating survey instruments will:

- Approximate a point source;
- Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified by National Institutes of Standards and Technology (NIST);
- Approximate the same energy and type of radiation as the environment in which the calibrated device will be employed; and
- For dose rate and exposure rate instruments, the source should be strong enough to give an exposure rate of at least about 7.7×10^{-6} coulombs/kilogram/hour (30 mR/hr) at 100 cm [e.g., 3.1 gigabecquerels (85 mCi) of Cs-137 or 7.8×10^{2} megabecquerels (21 mCi) of Co-60].

The three kinds of scales frequently used on dose or dose rate survey meters are calibrated as follows:

- Linear readout instruments with a single calibration control for all scales shall be adjusted at the point recommended by the manufacturer or at a point within the normal range of use. Instruments with calibration controls for each scale shall be adjusted on each scale. After adjustment, the response of the instrument shall be checked at approximately 20% and 80% of full scale. The instrument's readings shall be within ± 15% of the conventionally true values for the lower point and ± 10% for the upper point;
- Logarithmic readout instruments, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. The instrument shall be adjusted for each scale according to site specifications or the manufacturer's specifications. After adjustment, calibration shall be checked at a minimum of one point on each decade. Instrument readings shall have a maximum deviation from the conventionally true value of no more than 10% of the full decade value;
  - Meters with a digital display device shall be calibrated the same as meters with a linear scale;
  - Readings above 2.58×10^{-4} coulomb/kilogram/hour (1 R/hr) need not be calibrated, but such scales should be checked for operation and response to radiation; and
  - The inverse square and radioactive decay law should be used to correct changes in exposure rate due to changes in distance or source decay.

Surface Contamination Measurement Instruments

- Survey meters' efficiency must be determined by using radiation sources with similar energies and types of radiation that the survey instrument will be used to measure.
- If each scale has a calibration potentiometer, the reading shall be adjusted to read the conventionally true value at approximately 80% of full scale, and the reading at approximately 20% of full scale shall be observed. If only one calibration potentiometer is available, the reading shall be adjusted at mid-scale on one of the scales, and readings on the other scales shall be observed. Readings shall be within 20% of the conventionally true value.

Procedures for Calibrating, Liquid Scintillation Counters, Gamma Counters, Gas Flow Proportional Counters, and Multichannel Analyzers

A radioactive sealed source used for calibrating instruments will do the following:

- Approximate the geometry of the samples to be analyzed;
- Have its apparent source activity traceable by documented measurements to a standard certified by National Institutes of Standards and Technology (NIST); and
- Approximate the same energy and type of radiation as the samples that the calibrated device will be used to measure.

Calibration

- Calibration must produce readings within ± 20% of the actual values over the range of the instrument.
- Calibration of liquid scintillation counters will include quench correction.

Calibration Records

Calibration records, for all survey instruments, should indicate the procedure used and the data obtained.

The description of the calibration should include:

- The owner or user of the instrument;
- A description of the instrument, including the manufacturer's name, model number, serial number, and type of detector;
- A description of the calibration source, including the exposure rate at a specified distance or activity on a specified date;
- For each calibration point, the calculated exposure rate or count rate, the indicated exposure rate or count rate, the deduced correction factor (the calculated exposure rate or count rate divided by the indicated exposure rate or count rate), and the scale selected on the instrument;
- For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular);
- For instruments with internal detectors, the angle between radiation flux field and a specified surface of the instrument;
  - For detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure;
  - The exposure rate or count rate from a check source, if used; and
  - The name of the person who performed the calibration and the date it was performed.

The following information should be attached to the instrument as a calibration sticker or tag:

- For exposure rate meters, the source isotope used to calibrate the instrument (with correction factors) for each scale;
- The efficiency of the instrument, for each isotope the instrument will be used to measure (if efficiency is not calculated before each use);
- For each scale or decade not calibrated, an indication that the scale or decade was checked only for function but not calibrated;
- The date of calibration and the next calibration due date; and
- The apparent exposure rate or count rate from the check source, if used.

Air Sampler Calibration

In order to assess accurately the air concentration of radioactive materials in a given location, the volume of air sampled and the quantity of contaminant in the sample must be determined. Accurate determination of the volume of air sampled requires standard, reproducible, and periodic calibration of the air metering devices that are used with air sampling instruments.

The publication entitled '*Air Sampling Instruments*' found in the 7th Edition, American Conference of Governmental Industrial Hygienists, 1989, provides guidance on total air sample volume calibration methods acceptable to VDH staff, as supplemented below.

Frequency of Calibration

- A licensee committed to a routine or emergency air sampling program should perform an acceptable calibration of all airflow or volume metering devices at least annually (See NRC Regulatory Guide 8.25).
- Special calibrations should be performed at any time there is reason to believe that the operating characteristics of a metering device have been changed, by repair or alteration, or whenever system performance is observed to have changed significantly.
- Routine instrument maintenance should be performed as recommended by the manufacturer.
- Primary or secondary standard instruments used to calibrate air sampling instruments should be inspected frequently for consistency of performance.

Error Limit For Measurement of Air Sample Volume

Most methods of calibrating airflow or air volume metering devices require direct comparison to a primary or secondary standard instrument, to determine a calibration curve or a correction factor. An example of a primary standard is a spirometer that measures total air volume directly with high precision by liquid displacement. An example of a secondary standard is a wet-test meter that has been calibrated against a primary standard. Primary standards are usually accurate to within ± 1% and secondary standards to within ± 2%.

The following are significant errors associated with determining the total air volume sampled:

E_C: The error in determining the calibration factor. (An acceptable estimate is the percentage error associated with the standard instrument used in the calibration.)

E_S: Intrinsic error in reading the meter scale. (An acceptable estimate is the percentage equivalent of one-half of the smallest scale division, compared to the scale reading.)

E_t: The percentage error in measurement of sampling time that should be kept within 1%.

E_V: The most probable value of the cumulative percentage error in the determination of the total air volume sampled.

E_V: can be calculated from the following equation, provided there are no additional significant sources of errors:

$$E_V = [E_S^2 + E_C^2 + E_t^2]^{1/2}$$

The most probable value of the cumulative error E_V, in the determination of total volume, should be less than 20%.

A sample calculation of the most probable value of the cumulative error in total volume measured is as follows: If accuracies of the scale reading, the calibration factor, and sample time are ± 4, 2, and 1 %, respectively, and there are no other significant sources of error, the cumulative error would be:

$$E_V = [4^2 + 2^2 + 1^2]^{1/2} = 4.58\% \text{ or approx. } 5\%$$

If there are significant differences in pressure and temperature between the calibration site and the sampling site, appropriate corrections should be made using the ideal gas laws provided below:

$$Vs = V1 * (P1/760) * (273/T1)$$

Where Vs = volume at standard conditions (760 mm & 0^0 C)

V1 = volume measured at conditions P1 and T1

T1 = temperature of V1 in ^{0}K

P1 = pressure of V1 in mm Hg

Documentation of Calibration of Air Metering Devices

The licensee should maintain records of all routine and special calibrations of airflow or volume metering devices, including the primary or secondary standard used, method employed, and estimates of accuracy of the calibrated metering devices. All instruments should be clearly labeled as to the date and results of the most recent calibration and should include the appropriate correction factors to be used.

References:

- NRC Regulatory Guide 8.25, Revision 1, 'Air Sampling in the Workplace', which can be accessed at the NRC web site at www.nrc.gov.
- NRC NUREG - 1400, 'Air Sampling in the Workplace', which can be accessed at the NRC website at www.nrc.gov.
- The Health Physics & Radiological Health Handbook, Revised Edition, Edited by Bernard Shleien
- ANSI N323A-1997, 'Radiation Protection Instrumentation Test and Calibration.' Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018 or ordered electronically at the following address: http://www.ansi.org.
- 'Air Sampling Instruments,' American Conference of Governmental Industrial Hygienists, 1987

Appendix I:

Material Receipt and Accountability

Material Receipt and Accountability

Sample Procedure for Ordering and Receiving Radioactive Material

- The RSO should approve or place all orders for radioactive material and should ensure that the requested material, quantities, manufacturer, and model are authorized by the license and that the possession limits are not exceeded.
- During normal working hours, carriers should be instructed to deliver radioactive packages directly to the Radiation Safety Office (or designated receiving area).
- During off-duty hours, security or other designated trained personnel should accept delivery of radioactive packages in accordance with the procedure outlined in the sample memorandum below:

Sample Memorandum

Memorandum for Security Personnel

From: RSO, President, Vice President, etc.

Subject: Procedures for Receipt of Packages Containing Radioactive Material

If the package appears to be damaged, immediately contact the RSO. Ask the carrier to remain at the facility until it can be determined that neither the carrier nor the vehicle is contaminated.

Any packages containing radioactive material that arrive between (state times, e.g., 4:30 p.m. and 7:00 a.m. or on Saturdays or Sundays) shall be signed for by the security guard (or other designated trained individual) on duty and taken immediately to the designated receiving area. Security personnel (or other designated trained individual) should unlock the door, place the package in the designated secured storage area and re-lock the door.

Radiation Safety Officer (RSO): _____

Office Phone: _____

Home Phone: _____

Sample Instructions to Personnel Involved in Material Receipt

Shipping and Receiving Personnel

During normal working hours, immediately upon receipt of any package of licensed material, each package must be visually inspected for any signs of shipping damage such as crushed or punctured containers or signs of dampness. Any obvious damage must be reported to the RSO immediately. Do not touch any package suspected of leaking. Request the person delivering the package to remain until monitored by the RSO.

Outside of normal working hours (e.g., nights, weekends, and holidays), deliveries will usually be handled by security personnel (or other trained individuals) as described in the above procedures. Since certain packages of licensed material will have detectable external radiation, they should be sent immediately to a designated storage area, where they will be checked for contamination and external radiation level as soon as practical. They should not be allowed to remain in the receiving area any longer than necessary, as they may be a source of exposure for receiving personnel.

If the instructions are not clear, or if there are questions regarding receiving packages containing radioactive material, please contact:

Name _____

Phone _____

For additional information on worker training, see **Item 7** "Training for Individuals Working In or Frequenting Restricted Areas".

Sample Procedure for Safely Opening Packages Containing Licensed Materials

For packages received under the specific license, authorized individuals shall implement procedures for opening each package, as follows:

- Wear gloves to prevent hand contamination;
- Visually inspect the package for any sign of damage (e.g. crushed, punctured). If damage is noted, stop and notify the RSO;
- Check DOT White I, Yellow II, or Yellow III label or packing slip for activity of contents, so shipment does not exceed license possession limits;
- Monitor the external surfaces of a labeled package according to specifications in **12VAC5-481-3080**;

- Open the outer package (following supplier's directions if provided) and remove packing slip. Open inner package to verify contents (compare requisition, packing slip and label on the bottle or other container). Check integrity of the final source container (e.g., inspecting for breakage of seals or vials, loss of liquid, discoloration of packaging material, high count rate on smear). Again check that the shipment does not exceed license possession limits. If you find anything other than expected, stop and notify the RSO;
  - Survey the packing material and packages for contamination before discarding. If contamination is found, treat as radioactive waste. If no contamination is found, obliterate the radiation labels prior to discarding in the regular trash;
  - Maintain records of receipt, package survey, and wipe test results; and
  - Notify the final carrier, and by telephone or facsimile, VDH when removable radioactive surface contamination exceeds the limits of **49 CFR 173.44***;* or external radiation levels exceed the limits of **12VAC5-481-3070**.

Sample Transfer Policy Statements

Internal Transfers

Licensed materials that may be transferred from one department or AU's control to another should have prior approval from the RSO. A written transfer procedure should be developed by the RSO to ensure that transfers are done in accordance with the conditions of the license. All transfers shall be done in a way that minimizes the probability of spillage or breakage. Double containers should be used, including suitable shielding, for such transfers.

External Transfers

Licensed material shall not be transferred or shipped from one location to another without the approval of the RSO. Such transfers/shipments must be packaged and labeled in accordance with VDH, DOT, or U.S. Postal Service rules and regulations, whichever is applicable.

Appendix J
Guidance for Demonstrating that Individual Members of the Public will not Receive Doses Exceeding the Allowable Limit

Public Dose

This appendix describes methods for determining radiation doses to members of the public.

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 millisievert (mSv) [100 millirem (mrem)] in one calendar year resulting from the licensee's possession and/or use of licensed materials.
- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.
- Air emissions of radioactive material to the environment will not result in a TEDE in excess of 10 millirem (0.1 mSv) per year.

Members of the public include persons who live, work, study, or may be near locations where radioactive material is used or stored and employees whose assigned duties do not include the use of radioactive material but may work in the vicinity where such materials are used or stored.

Doses to Members of the Public	
INCLUDES doses from: * Radiation and/or radioactive material released by a licensee * Sources of radiation under the control of a licensee * Air effluents from sources of licensed radioactive materials	DOES NOT INCLUDE doses from: * Sanitary sewerage discharges from licensees * Natural background radiation * Medical administration of radioactive material * Voluntary participation in medical research

Typical unrestricted areas may include offices, shops, laboratories (where licensed material is not used or stored), areas outside buildings, property, and storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials, but the licensee may control access to these areas for other reasons, such as security.

The licensee may show compliance with the annual dose limit for individual members of the public by:

- Demonstrating by measurement or calculation that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv (100 mrem);
- Demonstrating that the annual average concentration of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area does not exceed the values specified in **12VAC5-481-3690,** and if an individual were continuously present in an unrestricted area the dose from external sources would not exceed 0.02 mSv (2 mrem) in an hour and 0.5 mSv (0.05 rem) in a year; and
- Demonstrating that air emissions of radioactive materials do not result in doses greater than the constraint limit of 0.1mSv (10 mrem) TEDE.

In order to perform a dose assessment, licensees should identify all potential sources of external and internal radiation exposure to members of the public and all locations of use, transport, and storage of radioactive material at their facilities. Licensees must then take radiation measurements or perform calculations to demonstrate compliance.

Measurements

The licensee may use measurements to demonstrate that the average annual releases are within regulatory limits, as well as to demonstrate that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv (100 mrem). These measurements may include:

- Dose rate surveys for radiation exposures from external radiation sources; and
- Measurements of radionuclides in air and water effluent.

The method used to measure dose will depend upon the nature of the radiation source. If the source of radiation is constant, it may be adequate to measure the dose rate and integrate it over time. If the source of radiation differs or changes over time, it may be necessary to perform continuous measurements.

Radioactivity releases may be determined by effluent monitoring or by effluent sampling and analysis. Airborne effluents may be discharged when volatile materials are used, such as during iodinations, but the discharge itself is usually not continuous since volatile materials are often used periodically rather than continuously. Liquid effluents may be discharged continuously or may be stored and subsequently discharged on a batch basis. For each type of source and for each route of potential exposure, consider the location of measurement points, whether continuous or periodic monitoring is required, the frequency of sampling and measurement, and any additional information. For discharges of airborne radionuclides, for example, it may be necessary to obtain information on the efficiency of filters and the air flow rate of the discharge system, as well as meteorological data and the distance to the nearest individual member of the public.

Calculation Method

Using a calculation method, the licensee must determine the highest dose an individual is likely to receive at the boundary of the unrestricted area. The licensee must take into account the individual's exposure from external sources and the concentration of radionuclides in gaseous and liquid releases. In practice, the licensee may wish to make conservative assumptions to simplify the dose calculation.

The public dose limit applies to the individual who is likely to receive the highest dose from licensed operations. Therefore, the dose calculations must consider the location with the potential for the highest internal and external exposures. A conservative calculation should assume that the individual was continuously present 24 hours a day, 365 days a year, or an occupancy factor of 1 (see **Table 8**). If the result of the calculation using an occupancy factor of 1 demonstrates that the public dose limit is not exceeded, then there is no need for further evaluation.

If the calculation demonstrates that the public dose limit is exceeded with an occupancy factor of 1, then more realistic assumptions of the individual's occupancy at the points of highest internal and external exposures may be made. The licensee may use the occupancy factors in **Table 8** or may calculate a specific occupancy factor by determining the likely fraction of time that the individual is present.

Table 8: Standard Occupancy Factors

Occupancy Factor	Description
1	Work areas such as offices, laboratories, shops, and occupied space in nearby buildings or outdoor areas
1/4	Corridors, lounges, elevators using operators, unattended parking lots
1/16	Waiting rooms, rest rooms, stairways, unattended elevators, janitor's closets, outside areas used only for pedestrians or vehicular traffic

Records

The licensee must maintain records to demonstrate compliance with the dose limit for individual members of the public until VDH terminates the license. In general, survey and monitoring records of ambient radiation and effluent radioactivity should be adequate.

Records demonstrating the dose to an individual member of the public should identify the instruments used in the survey, the name of the surveyor, the date of the survey, the location of the survey(s) including a description or drawing of the area surveyed, survey results, and if applicable, the occupancy factors used and justification for their use. In addition, records demonstrating the dose to an individual member of the public that involve effluent sampling analysis should include information on concentrations of specific radionuclides, minimum detectable activity of the system and the estimated uncertainty of measurements.

Appendix K

General Topics for Safe Possession and Use of Radioactive Materials and Model Emergency Procedures

General Topics for Safe Use of Radioisotopes

Each work area where radioactive material is used or stored should have general rules, so that workers know what is required. Typical instructions should include:

- Wear a protective clothing at all times in areas where licensed materials are used;
- Wear disposable gloves at all times when handling licensed materials;
- After each procedure or before leaving the area, monitor hands, shoes, and clothing for contamination in a low-background area;
- Do not eat, drink, smoke or apply cosmetics in any area where licensed material is stored or used;
- Do not store food, drink or personal effects in areas where licensed material is stored or used;
- Wear personnel monitoring devices, if required, at all times while in areas where licensed materials are used or stored;
- Dispose of radioactive waste only in designated, labeled and properly shielded receptacles;
- Never pipette by mouth;
- Store radioactive solutions in clearly labeled containers; and
- Secure all licensed material when it is not under the constant surveillance and immediate control of the user(s).

Storage of Food and Drink

Food or drink shall not be stored in refrigerators with radioisotopes.

Radionuclides-Specific Procedures

Licensees should develop written procedures for use of different radionuclides so that users know the types of shielding, protective clothing, survey instruments, surveys, and decontamination activities that are required. Examples of such procedures are included below.

Example 1:

If requesting more than 37 MBq (1 mCi) of iodine-125 or iodine-131, special safety instructions should be provided to users, including the following:

- A mandatory radiation survey and wipe test for radioactive contamination after each use;
- Bioassay procedures for individuals working with millicurie quantities of radioiodine;
- The use of vented hoods for iodination and for the storage of millicurie quantities of radioiodine;
- A dry run prior to the performance of unfamiliar procedures, in order to preclude unexpected complications. In addition, it is recommended that the RSO be present during new procedures; and
- Procedures for measuring the concentration of radioiodine effluents from the hoods.

Example 2:

If requesting more than 37 MBq (1 mCi) of phosphorus-32, special safety instructions should be provided to users, including the following:

- The use of low-density plastic shielding in order to keep bremsstrahlung radiation to a minimum;
- A mandatory radiation survey and wipe test for radioactive contamination after each use;
- The use of extremity monitors for procedures that involve one millicurie or more;
- A dry run prior to the performance of unfamiliar procedures in order to preclude unexpected complications. In addition, it is recommended that the RSO be present during new procedures; and
- The use of eye protection for procedures that involve 10 millicuries or more.

Model Procedures for Handling Emergencies

Appropriate first aid and other immediate medical needs of injured individuals should not be neglected, delayed, or ignored due to suspected contamination.

General Safety Procedures to Handle Spills

Name and telephone number of RSO or an alternate person(s) should be posted conspicuously in areas of use, so that it is readily available to workers in case of emergencies. Licensee should have emergency equipment readily available for handling spills. Spill kits should include the following:

- Disposable gloves;
- Housekeeping gloves;
- Disposable lab coats;
- Disposable head coverings;
- Disposable shoe covers;
- Roll of absorbent paper with plastic backing;
- Masking tape;
- Plastic trash bags with twist ties;
- "Radioactive Material" labeling tape;
- Marking pen;
- Pre-strung "Radioactive Material" labeling tags;
- Box of Wipes;
- Instructions for "Emergency Procedures";
- Clipboard with a copy of the Radioactive Spill Report Form for the facility;
- Pencil; and
- Appropriate survey instruments including batteries (for survey meters).

Minor Spills of Liquids and Solids

- Instructions to Workers
  - Notify persons in the area that a spill has occurred.
  - Prevent the spread of contamination by covering the spill with absorbent paper. (Paper should be dampened if solids are spilled).

- Clean up the spill, wearing disposable gloves and using absorbent paper.
- Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Put contaminated gloves and any other contaminated disposable material in the bag.
- Survey the area with an appropriate low-range radiation detector survey meter or other appropriate technique. Check the area around the spill for contamination. Also check hands, clothing, and shoes for contamination.
- Report the incident to the Radiation Safety Officer (RSO) promptly.
- Allow no one to return to work in the area unless approved by the RSO.
- Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO
  - Follow up on the decontamination activities and document the results;
  - As appropriate, determine cause and corrective actions needed; consider bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin; and
  - If necessary, notify VDH.

Major Spills of Liquids and Solids

- Instructions to Workers
  - Clear the area. If appropriate, survey all persons not involved in the spill and vacate the room;
  - Prevent the spread of contamination by covering the spill with absorbent paper (paper should be dampened if solids are spilled), but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated;
  - Shield the source only if it can be done without further contamination or significant increase in radiation exposure;
  - Close the room and lock or otherwise secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred;
  - Notify the RSO immediately;
  - Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with a mild soap;
  - Allow no one to return to work in the area unless approved by the RSO;
  - Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples); and
  - Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO

- Confirm decontamination of personnel. If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration;
- Supervise decontamination activities and document the results. Documentation should include location of surveys and decontamination results;
- Determine cause and needed corrective actions; consider need for bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin; and
- If necessary, notify VDH.

Incidents Involving Radioactive Dusts, Mists, Fumes, Organic Vapors, and Gases

- Instructions to Workers
  - Notify all personnel to vacate the room immediately;
  - Shut down ventilation system, if appropriate, to prevent the spread of contamination throughout system and other parts of facility;
  - Vacate the room. Seal the area, if possible;
  - Notify the RSO immediately;
  - Ensure that all access doors to the area are closed and posted with radiation warning signs, or post guards (trained) at all access doors to prevent accidental opening of the doors or entry to the area;
  - Survey all persons who could have possibly been contaminated. Decontaminate as directed by the RSO;
  - Promptly report suspected inhalations and ingestions of licensed material to the RSO;
  - Decontaminate the area only when advised and/or supervised by the RSO;
  - Allow no one to return to work in the area unless approved by the RSO;
  - Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples); and
  - Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision and collection of bioassay samples, requested documentation).

- Reminders to RSO
  - Supervise decontamination activities;
  - Perform air sample surveys in the area before permitting resumption of work with licensed materials;
  - Provide written directions to potentially contaminated individuals about providing and collecting urine, breath, blood, or fecal samples, etc;
  - Consider need for medical exam and/or whole body count before permitting involved individuals to return to work with licensed material;
  - Determine cause and corrective actions needed; consider need for bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin.
  - Document incident; and
  - If necessary, notify VDH.

Minor Fires

- Instructions to Workers
  - Immediately attempt to put out the fire by approved methods (i.e., fire extinguisher) if other fire hazards or radiation hazards are not present;
  - Notify all persons present to vacate the area and have one individual immediately call the RSO and fire department (as instructed by RSO);
  - Once the fire is out, isolate the area to prevent the spread of possible contamination;
  - Survey all persons involved in combating the fire for possible contamination;
  - Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with a mild soap;
  - In consultation with the RSO, determine a plan of decontamination and the types of protective devices and survey equipment that will be necessary to decontaminate the area;
  - Allow no one to return to work in the area unless approved by the RSO;
  - Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples); and
  - Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO
  - Supervise decontamination activities;
  - If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration;
  - Consult with fire safety officials to assure that there are no other possibilities of another fire starting;
  - Determine cause and needed corrective actions; consider need for bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin.
  - Document incident; and
  - If necessary, notify VDH.

Fires, Explosions, or Major Emergencies

- Instructions to Workers
  - Notify all persons in the area to leave immediately;
  - Notify the fire department;
  - Notify the RSO and other facility safety personnel;
  - Upon arrival of firefighters, inform them where radioactive materials are stored or where radioisotopes were being used; inform them of the present location of the licensed material and the best possible entrance route to the radiation area, as well as any precautions to avoid exposure or risk of creating radioactive contamination by use of high pressure water, etc;
  - Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples);

- Allow no one to return to work in the area unless approved by the RSO; and
- Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO
  - Coordinate activities with facility's industrial hygienist or environmental health & safety office, and with local fire department;
  - Consult with the firefighting personnel and set up a controlled area where the firefighters can be surveyed for contamination of their protective clothing and equipment after the fire is extinguished;
  - Once the fire is extinguished, do not allow the firefighters to enter the radiation area until a thorough evaluation and survey are performed to determine the extent of the damage to the licensed material use and storage areas;
  - Perform thorough contamination surveys of the firefighters and their equipment before they leave the controlled area and decontaminate, if necessary;
  - Supervise decontamination activities;
  - Consider bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin.
  - Document incident; and
  - If necessary, notify VDH.

Note: The telephone number for VDH during normal business hours (8:00 a.m. - 4:30 p.m.) is **(804) 864-8150**. After normal business hours, the emergency telephone numbers are **(804) 674-2400** or **(800) 468-8892.** Indicate radiological emergency.

Copies of emergency procedures must be provided to all users. Post a current copy in each area where radioactive material is used and/or stored.

Appendix L

Typical Notification and Reporting Requirements

Table 9: VDH Notifications and/or Reports

Event	Telephone Notification	Written Report	Regulatory Requirement
Theft or loss of material	Immediate	30 days	**12VAC5-481-1090**
Whole body dose greater than 0.25 Sv (25 rems)	Immediate	30 days	**12VAC5-481-1100 12VAC5-481-1110**
Extremity dose greater than 2.5 Sv (250 rems)	Immediate	30 days	**12VAC5-481-1100 12VAC5-481-1110**
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	**12VAC5-481-1100 12VAC5-481-1110**
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	**12VAC5-481-1100 12VAC5-481-1110**
Whole body dose greater than 0.05 Sv (5 rems)	None	30 days	**12VAC5-481-1110**
Dose to individual member of public greater than 1 mSv (100 mrem)	None	30 days	**12VAC5-481-1110**
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	Immediate	30 days	**12VAC5-481-1100**
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	**12VAC5-481-1100**
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	**12VAC5-481-1100**

Note: Telephone notifications shall be made to VDH at (804) 864-8150 during normal business hours (8 a.m. – 4:30 p.m.). VDEM's 24 hour emergency telephone number is (800) 468-8892. Identify the emergency as radiological.

Appendix M

Radiation Safety Survey Topics

Radiation Safety Survey Topics

This Appendix provides applicants and licensees with additional information on surveys, including training requirements, survey frequency, contamination limits, and bioassays.

Training

Before allowing an individual to perform surveys, the RSO will ensure that he or she has sufficient training and experience to perform surveys independently.

Academic training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection;
- Radioactivity measurements, monitoring techniques, and using instruments;
- Mathematics and calculations basic to using and measuring radioactivity; and
- Biological effects of radiation.

Appropriate on-the-job-training consists of the following:

- Observing authorized personnel using survey equipment, collecting samples, and analyzing samples; and
- Using survey equipment, collecting samples, and analyzing samples under the supervision and in the physical presence of an individual authorized to perform surveys.

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, survey samples will be analyzed in a low-background area.
- A gamma counter system with a single or multi-channel analyzer can be used to count samples containing gamma-emitters (e.g., Cs-137, Co-60).
- A liquid scintillation or gas-flow proportional counting system can be used to count samples containing alpha-emitters, beta-emitters, and gamma-emitters (if efficiency is great enough to achieve the required sensitivity for measurements).

Ambient Radiation Level Surveys

- Dose-rate surveys, at a minimum, should be performed in locations where workers are exposed to radiation levels that might result in radiation doses in excess of 10% of the occupational dose limits or where an individual is working in a dose rate of 0.025 mSv (2.5 mrem/hr) or more (50 mSv/year divided by 2,000 hr/year).
- **12VAC5-481-720** requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year and the dose in any unrestricted area from external sources does not exceed 0.02 mSv (2 mrem) in any one hour.

The frequency of ambient surveys depends on the quantity and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect the worker and members of the public from external exposure to radiation. While the rule does not specify a specific survey frequency, the licensee is required to ensure that the dose rate limits are not exceeded.

Contamination Surveys

Licensees' contamination surveys should be sufficient to identify areas of contamination that might result in doses to workers or to the public. Combined removable and fixed contamination should be surveyed using appropriate radiation detection equipment. Removable contamination can be detected and measured through a wipe test of the surface, which is counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

Contamination surveys should be performed:

- To evaluate radioactive contamination that could be present on surfaces of floors, walls, work area furniture, and equipment;
- After any spill or contamination event;
- When procedures or processes have changed;
- To evaluate the potential contamination of users and the immediate work area, at the end of the day or prior to leaving the area of use, when licensed material is used;
- In unrestricted areas at frequencies consistent with the types and quantities of materials in use but generally not less frequently than quarterly; and
- In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.

Contamination Survey Frequency

Personnel should survey for contamination in locations where individuals are working with an unsealed form of radioactive material. These surveys should be done at a frequency appropriate to the types and quantities of radioactive materials in use. If the activity used is greater than or equal to the smallest annual limit on intake (ALI) (for either inhalation or ingestion) as identified in **12VAC5-481-3690**, then documented surveys should be performed at least daily in accordance with **12VAC5-481-750**.

Table 10 contains suggested contamination survey frequencies based on ALIs. The suggested frequency of surveys is based upon the amount of licensed material "in use" at any one time at any particular location. If licensed material has not been used for a period of time greater than the required survey frequency, then it is considered to be "not in use."

Table 10: Suggested Contamination Survey Frequency

	< 0.1 ALI	**≥ 0.1 ALI < 1.0**	**≥ 1.0 ALI**
In Use	Monthly	Weekly	Daily
Not in Use	Every 6 Months		

Contamination in Unrestricted Areas

Contamination found in unrestricted areas should be immediately decontaminated to background levels. When it is not possible to get to background levels, the licensee must ensure that the amounts do not exceed the contamination levels listed in **Table 11.**

Table 11: Acceptable Surface Contamination Levels for Equipment

Nuclide[a]	Average[b, c]	Maximum[b, d]	Removable[b, e]
I-125, I-129	1.7 Bq*/100 cm^2 (100 dpm/100 cm^2)	5.0 Bq/100 cm^2 (300 dpm/100 cm^2)	0.3 Bq/100 cm^2 (20 dpm/100 cm^2)
I-126, I-131, I-133, Sr-90	16.7 Bq/100 cm^2 (1,000 dpm/100 cm^2)	50.0 Bq/100cm^2 (3,000 dpm/100 $cm^{2)}$	3.3 Bq/100cm^2 (200 dpm/100 cm^2)
Alpha emitters	8.33Bq/100 cm^2 (500 dpm/100 $cm^{2)}$	25 Bq/100 cm^2 (1500 dpm/100 cm^2)	1.67 Bq/100 cm^2 (100 dpm/100 cm^2)
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	83.3 Bq*/100 cm^2 (5,000 dpm/100 cm^2)	250 Bq/100 cm^2 (15,000 dpm /100 cm^2)	16.7 Bq/100 cm^2 (1,000 dpm/100 cm^2)

[a] Where surface contamination by both alpha- and beta-gamma-emitting nuclides exists, the limits established for alpha- and beta-gamma-emitting nuclides should apply independently.
[b] As used in this table, dpm (disintegration per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.
[c] Measurements of average contaminant should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.
[d] The maximum contamination level applies to an area of not more than 100 cm^2.
[e] The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.
* 1 Bq = 1 Disintegration per second

When equipment or facilities that are potentially contaminated are to be released for unrestricted use, **Table 11** provides the maximum acceptable residual levels for equipment and **Table 12** provides screening values for building surface contamination. To the extent practicable, it is appropriate to decontaminate below these levels. Surface contamination surveys should be conducted for both removable and fixed contamination before these facilities or equipment are released from restricted to unrestricted use, to ensure that they meet these limits.

A standardized method for smear testing of a relatively uniform area should be used to aid in comparing contamination at different times and places. A smear taken from an area of about 100 cm^2 is acceptable to indicate levels of removable contamination.

Table 12: Screening Values for Building Surface Contamination[1]

Radionuclide	Symbol	Screening levels for unrestricted release (dpm/100 cm^2)
Hydrogen-3 (Tritium)	H-3	1.2×10^8
Carbon-14	C-14	3.7×10^6
Sodium-22	Na-22	9.5×10^3
Sulfur-35	S-35	1.3×10^7
Chlorine-36	Cl-36	5.0×10^5
Manganese-54	Mn-54	3.2×10^4
Iron-55	Fe-55	4.5×10^6
Cobalt-60	Co-60	7.1×10^3
Nickel-63	Ni-63	1.8×10^6
Strontium-90	Sr-90	8.7×10^3
Technetium-99	Tc-99	1.3×10^6
Iodine-129	I-129	3.5×10^4
Cesium-137	Cs-137	2.8×10^4
Iridium-192	Ir-192	7.4×10^4

[1] Screening levels are based on the assumption that the fraction of removable surface contamination is equal to 0.1. For cases when the fraction of removable contamination is undetermined or higher than 0.1, users may assume, for screening purposes, that 100% of surface contamination is removable; and therefore the screening levels should be decreased by a factor of 10. Alternatively, users having site-specific data on the fraction of removable contamination (e.g., within 10% to 100% range) may calculate site-specific screening levels using D and D Version 1.

Table 12 does not include screening values for radionuclides that emit alpha particles or for soil contamination. For such sites, licensees are encouraged to use, in the interim period, site-specific dose assessment based on actual site physical and environmental conditions.

Units are disintegrations per minute per 100 square centimeters (dpm/100 cm^2). 1 dpm is equivalent to 0.0167 becquerel (Bq). The screening values represent surface concentrations of individual radionuclides that would be deemed in compliance with the 0.25 mSv/yr (25 mrem/yr) unrestricted release dose limit in **12VAC5-481-1161**. For radionuclides in a mixture, the "sum of fractions" rule applies; see **12VAC 5-481-3690**. Refer to NRC NUREG-1727 '*NMSS Decommissioning Standard Review Plan*' for further information on application of the values in this table.

Table 12 was derived using the D and D screening code, Version 1, and its default input parameters. **Table 12** provides criteria which permit licensees to demonstrate compliance with the unrestricted release dose criterion in the license termination rule. The values correspond to screening "derived concentration guidelines" for each specific radionuclide based on the methodology described in NRC NUREG-1727 '*NMSS Decommissioning Standard Review Plan*'. Sites with building surface contamination levels below those listed in **Table 12** would be deemed acceptable for release for unrestricted use in accordance with the dose criteria in **12VAC5-481-1161**, provided that residual radioactivity has been reduced to ALARA levels. The table is intended for use as criteria to facilitate license termination for many simple routine decommissioning cases without a site-specific dose assessment. For facilities with contamination levels above those in **Table 12**, additional site-specific dose assessments may be necessary, and licensees should refer to NRC NUREG-1727 '*NMSS Decommissioning Standard Review Plan*' regarding acceptable methods for conducting the appropriate dose assessment.

References: The D and D code can be installed by downloading the self-extracting program file, setup.exe, accessed through the web site: http://techconf.llnl.gov/radcri/java.html. NUREG-1727 '*NMSS Decommissioning Standard Review Plan*', NRC NUREG - 1549, 'Decision Methods for Dose Assessment to Comply With

Radiological Criteria for License Termination,' dated July 1998, and NRC NUREG/CR - 5512, Vol. #3, 'Residual Radioactive Contamination From Decommissioning, Parameter Analysis,', can also be accessed through NRC's web site at www.nrc.gov.

Survey Record Requirements

Each survey record should include the following:

- A diagram of the area surveyed (See **Figure 3**);
- A list of items and equipment surveyed;
- Specific locations on the survey diagram where a wipe test was taken;
- Ambient radiation levels with appropriate units;
- Contamination levels with appropriate units;
- Make and model number of instruments used;
- Background levels; and
- Name of the person making the evaluation and recording the results and date.

Licensees should record contamination levels observed and procedures followed for incidents involving contamination of individuals. The record should include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor's signature.

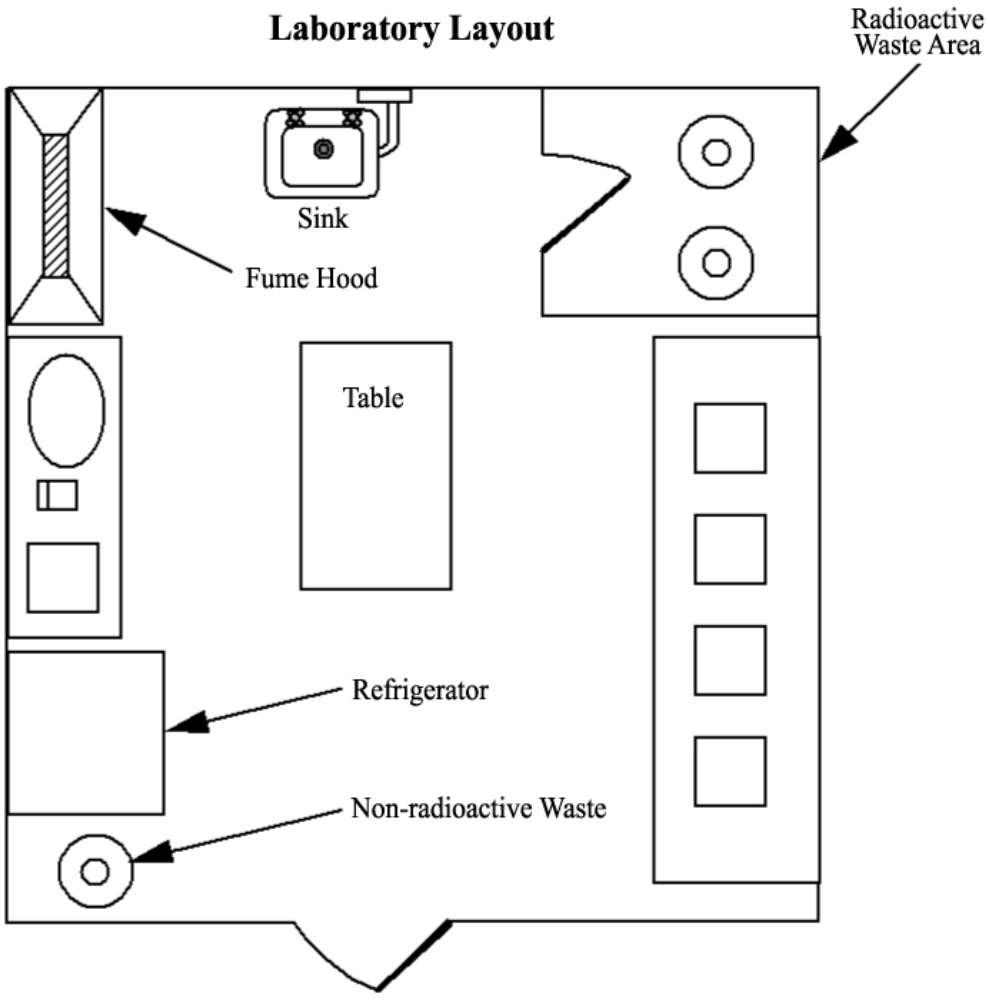


Figure 3: Laboratory Layout.

Air Monitoring in the Workplace

Air sampling can be used to do the following:

- Determine whether the confinement of radioactive materials is effective;
- Measure airborne radioactive material concentrations in the workplace;
- Estimate worker intakes of radioactive material;
- Determine posting requirements;
- Determine what protective equipment and measures are appropriate; and
- Warn of significantly elevated levels of airborne radioactive materials.

If bioassay measurements are used to determine worker doses of record, air sampling may be used to determine time of intake and to determine which workers should have bioassay measurements. The use of engineering controls and a good air sampling program may eliminate need for bioassays.

Refer to NRC Regulatory Guide 8.25, Revision 1, '*Air Sampling in the Workplace*' and NRC NUREG - 1400, '*Air Sampling in the Workplace*' for further guidance on the air sampling.

Airborne Effluent Release Monitoring

When practicable, airborne radioactive effluents should be released from monitored release points (e.g., monitored stacks, discharges, vents) to provide accurate measurements to estimate public exposure. Licensees should verify the performance of effluent monitoring systems by regular calibration (at least annually) to ensure their reliability.

NRC Regulatory Guide 4.20, '*Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors*', provides guidance on methods acceptable (calculation or COMPLY code) to the agency for compliance with the constraint on air emissions to the environment.

NRC Regulatory Guide 8.37, *'ALARA Levels for Effluents from Materials Facilities,'*, provides guidance on designing an acceptable program for establishing and maintaining ALARA levels for gaseous and liquid effluents at materials facilities.

For release points for which monitoring are not practicable, the licensee should estimate the magnitude of the unmonitored effluents. These unmonitored releases will occur anytime unsealed material is handled outside a fume hood or other device that will control the releases. The licensee should include these estimates when demonstrating compliance with dose limits and ALARA goals. Unmonitored releases may be estimated based on the quantity of material used in these areas or the number of procedures performed or other appropriate methods. The unmonitored effluents should not exceed 30% of the total estimated effluent releases or 10% of the permissible air effluent in **12VAC5-481-3690,** whichever is greater.

Effluent monitoring systems should be designed in accordance with ANSI N13.1 (1969), '*Document to Sampling Airborne Radioactive Materials in Nuclear Facilities*' and ANSI N42.18, '*Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents*.'

Liquid Effluent Release Monitoring

The licensee should evaluate the concentrations of radioactive material in water that is released to the environment and to the sanitary sewer. The licensee must show that these releases meet the limits in **12VAC5-481-720** and **12VAC5-481-930**, respectively.

The topic of sanitary sewerage releases is more fully discussed in **Appendix P**.

Bioassay Monitoring

Frequency of Required Bioassay Measurements

Determining the appropriate frequency of routine bioassay measurements depends upon the exposure potential and the physical and chemical characteristics of the radioactive material and the route of entry to the body. Consider the following elements:

- Potential exposure of the individual;
- Retention and excretion characteristics of the radionuclides;
- Sensitivity of the measurement technique; and
- Acceptable uncertainty in the estimate of intake and committed dose equivalent.

Bioassay measurements used for demonstrating compliance with the occupational dose limits should be conducted often enough to identify and quantify potential exposures and resultant intakes that, during any year, are likely to collectively exceed 0.1 times the ALI. The 10% ALI criterion is consistent with **12VAC5-481-760,** which requires licensees to monitor intakes and assess occupational doses for exposed individuals who are likely to exceed 10% of the applicable limit (i.e., intakes likely to exceed 0.1 ALI for adults).

Separate categories of bioassay measurements, routine measurements and special measurements further determine the frequency and scope of measurements.

Routine Measurements

Routine measurements include baseline measurements, periodic measurements, and termination measurements. These measurements should be conducted to confirm that appropriate controls exist and to assess dose. The method of bioassay selected (for example, whole body counting, urinalysis, etc) and the samples collected will vary according to the radionuclide and the compound to which it is attached. Sample collection procedures should be developed to ensure that appropriate types, sizes, and numbers of samples are collected that will provide appropriate physiological information for the dose assessment.

An individual's baseline measurement of radioactive material within the body should be conducted before beginning work that involves exposure to radiation or radioactive materials for which monitoring is required.

In addition to the baseline measurements, periodic bioassay measurements should be performed. The frequency of periodic measurements should be based on the likelihood of significant exposure of the individual. In determining the worker's likely exposure, consider such information as the worker's access, work practices, measured levels of airborne radioactive material, and exposure time. Periodic measurements should be made when the cumulative exposure to airborne radioactivity, since the most recent bioassay measurement, is > 0.02 ALI (40 DAC hours). Noble gases and airborne particulates with a radioactive half-life of less than 2 hours should be excluded from the evaluation, since external exposure generally controls these radionuclides.

At a minimum, periodic measurements should be conducted annually. Periodic measurements provide additional information on any long-term accumulation and retention of radioactive material in the body, especially for exposures to concentrations of airborne radioactive material below monitoring thresholds.

When an individual is no longer subject to the bioassay program, because of change in employment status, termination bioassay measurement should be made, when practicable, to ensure that any unknown intakes are quantified.

Collection of Emergency Bioassay Samples

In the event of an emergency where an individual became contaminated and radioactive material was taken into the body through skin absorption or other means, or is suspected of having ingested or inhaled radioactive material, an estimate of the amount of material taken into the body may be required. Frequently, this estimate is made by performing bioassay of the individual. Bioassays may be performed through direct methods such as whole body counting or thyroid counting, where the radioactive material in the body can be directly measured using appropriate instruments. Bioassays may also be performed through indirect means such as sampling urine or other excreta from the body and calculating the intake and sample collection, and knowledge of the rate of excretion of the compound and/or radionuclide from the body. While there are many ways to perform the calculations, including using computer models, the method of calculation is only as good as the quality of the samples and analysis performed. Because a dose estimate may be required, bioassay procedures for suspected intake may differ from those in a routine bioassay screening program, and the radiation safety program should include procedures and equipment for appropriate sample collection in an emergency. The following items should be considered in developing these procedures:

- Type of bioassay that must be performed (direct or indirect)
- Number of samples or data points to be collected
- Frequency of sampling (hourly, daily, weekly, once, etc)
- Size of the sample to be collected (24 hour urine collection)
- Ease/difficulty of sample collection
- Need for written instructions to be provided to the sample collector who may be the contaminated individual

Special Monitoring

Because of uncertainty in the time of intakes and the absence of other data related to the exposure (e.g., physical and chemical forms, exposure duration), correlating positive results to actual intakes for routine measurements can sometimes be difficult. Abnormal and inadvertent intakes from situations such as a failed respiratory protective device, inadequate engineering controls, inadvertent ingestion, contamination of a wound, or skin absorption, should be evaluated on a case-by-case basis. When determining whether potential intakes should be evaluated, consider the following circumstances:

- The presence of unusually high levels of facial and/or nasal contamination;
- Entry into airborne radioactivity areas without appropriate exposure controls;
- Operational events with a reasonable likelihood that a worker was exposed to unknown quantities of airborne radioactive material (e.g., loss of system or container integrity);
- Known or suspected incidents of a worker ingesting radioactive material;
- Incidents that result in contamination of wounds or other skin absorption; and
- Evidence of damage to or failure of a respiratory protective device.

References: Can be accessed through the NRC's web site at www.nrc.gov and ANSI's web site at www.ansi.org.

- NUREG-1727 *'NMSS Decommissioning Standard Review Plan'*

- Federal Register Notice, *'Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination,'* Volume 63, Number 222, Page 64132,
- NRC Regulatory Guide 4.20, *'Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors,'*
- NRC Regulatory Guide 8.9, Revision 1, *'Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program,'*
- NRC Regulatory Guide 8.23, Revision 1, *'Radiation Safety Surveys at Medical Institutions,'* NRC Regulatory Guide 8.25, Revision 1, *'Air Sampling in the Workplace,'*
- *N*RC Regulatory Guide 8.32, *'Criteria for Establishing a Tritium Bioassay Program,'*
- NRC Regulatory Guide 8.37, *'ALARA Levels for Effluents from Materials Facilities,'*
- NUREG - 1400, *'Air Sampling in the Workplace,'*
- NUREG - 1549, *'Decision Methods for Dose Assessment to Comply With Radiological Criteria for License Termination,'*
- NUREG/CR - 5512, Vol. #3, *'Residual Radioactive Contamination From Decommissioning, Parameter Analysis,'* NUREG/CR - 4884, *'Interpretation of Bioassay Measurements,'*
- *Additional References*
- *ANSI* N13.1 (1969), *'Document to Sampling Airborne Radioactive Materials in Nuclear Facilities,'*
- ANSI N42.18, *'Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents,'*
- NCRP Commentary No. 3, *'Screening Techniques for Determining Compliance with Environmental Standards*'.

Appendix N

Model Leak Test Program

Leak Test Procedures

This appendix provides applicants and licensees with leak test procedures and sample calculations for determining activity on a wipe test sample.

Frequency for Conducting Leak Tests of Sealed Sources

Leak tests will be conducted at 6 month intervals or as specified in the respective SSD Registration Certificate.

Procedure for Performing Leak Testing and Analysis

For each source to be tested, list identifying information such as manufacturer, model number, serial number, radionuclides, and activity.

- If available, use a survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area (but not directly from the surface of a source) where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 185 becquerels (0.005 microcurie) of the radionuclides and ensure that its calibration is current.
- Using the selected instrument, count and record background count rate.
- Calculate efficiency.

For example: $\frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of std in Bq}} = \text{efficiency in cpm/Bq}$

Where: cpm = counts per minute
std = standard
bkg = background
Bq = becquerel

- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in becquerels (or microcuries).

For example: $\frac{[(\text{cpm from wipe sample}) - (\text{cpm from bkg})]}{\text{efficiency in cpm/Bq}} = \text{Bq on wipe sample}$

- Sign and date the list of sources, data and calculations. Retain records for 5 years (**12VAC5-481-1010**).
- If the wipe test activity is 185 Bq (0.005 Ci) or greater, make appropriate notications, so that the source can be withdrawn from use, disposed of properly, and VDH notified in writing within 5 days.

Appendix O

Transportation

Transportation

Part 1: Major DOT Regulations

The major areas in the DOT regulations that are most relevant for transportation of licensed material shipped as Type A quantities are as follows:

- Hazardous Materials Table: **49 CFR 172.101, App. A**, **Subpart B**, list of hazardous substances and reportable quantities (RQ), Table 2: Radionuclides
- Shipping Papers: **49 CFR 172.200-204**: General entries, description, additional description requirements, shipper's certification
- Package Markings: **49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324**: General marking requirements for non-bulk packagings, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging
- Package Labeling: **49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440**: General labeling requirements, prohibited labeling, radioactive materials, placement of labels, specifications for radioactive labels
- Placarding of Vehicles: **49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.510; 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556**: Applicability, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, specifications for RADIOACTIVE placards
- Emergency Response Information: **Subpart G, 49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604**: Applicability and general requirements, emergency response information, emergency response telephone number
- Training: **Subpart H, 49 CFR 172.702, 49 CFR 172.704**: Applicability and responsibility for training and testing, training requirements
- Shippers - General Requirements for Shipments and Packaging: **Subpart I, 49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.412, 49 CFR 173.415, 49 CFR 173.431, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.443, 49 CFR 173.448, 49 CFR 173.475, 49 CFR 173.476**: Definitions, general design requirements, additional design requirements for Type A packages, authorized Type A packages, activity limits for Type A packages, requirements for determining A_1 and A_2, table of A_1 and A_2 values for radionuclides, radiation level limitations, contamination control, general transportation requirements, quality control requirements prior to each shipment, approval of special form radioactive materials
- Radiation Protection Program for Shippers and Carriers: **Subpart I, 49 CFR 172.800, 49 CFR 172.802, 49 CFR 172.804:** Applicability of the radiation protection program, radiation protection program, record keeping, and notifications
- Carriage by Public Highway - General Information and Regulations: **Subpart A, 49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842:** Driver training, shipping paper, general requirements (secured against movement), Class 7 (radioactive) material.

Part 2: Sample Shipping Documents, Placards and Labels

Hazard Communications for Class 7 (Radioactive) Materials

DOT Shipping Papers (49 CFR 172.200-205)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Entries Always Required Unless Excepted	Additional Entries Sometimes Required	Optional Entries
! The basic description, in sequence: Proper Shipping Name, Hazard Class (7), U.N. Identification Number ! 24 hour emergency response telephone number ! Name of shipper ! Proper page numbering (Page 1 of 4) ! Except for empty and bulk packages, the total quantity (mass, or volume for liquid), in appropriate units (lbs, mL....) ! If not special form, chemical and physical form ! The name of each radionuclide (95% rule) and total package activity. The activity must be in SI units (e.g., Bq, TBq), or both SI units and customary units (e.g., Ci, mCi). However, for domestic shipments, the activity *may* be expressed in terms of customary units only, until 4/1/97. ! For each labeled package: - The category of label used; - The transport index of each package with a Yellow-II or Yellow-III label ! Shipper's certification (not required of private carriers)	Materials-Based Requirements: ! If hazardous substance, "RQ" as part of the basic description ! The LSA or SCO group (e.g., LSA-II) ! "Highway Route Controlled Quantity" as part of the basic description , if HRCQ ! Fissile material information (e.g., "Fissile Exempt," controlled shipment statement [see §172.203(d)(7)]) ! If the material is considered hazardous waste and the word waste does not appear in the shipping name, then "waste" must precede the shipping name (e.g., Waste Radioactive Material, nos, UN2982) ! "Radioactive Material" if not in proper shipping name Package-Based Requirements: ! Package identification for DOT Type B or NRC certified packages ! IAEA CoC ID number for export shipments or shipments using foreign-made packaging (see §173.473) Administrative-Based Requirements: ! "Exclusive Use-Shipment" ! Instructions for maintenance of exclusive use-shipment controls for LSA/SCO strong-tight or NRC certified LSA (§ 173.427) ! If a DOT exemption is being used, "DOT-E" followed by the exemption number	! The type of packaging (e.g., Type A, Type B, IP-1, ...) ! The Technical/chemical name may be in included (if listed in §172.203(k), in parentheses between the proper shipping name and hazard class; otherwise inserted in parenthesis after the basic description) ! Other information is permitted (e.g., functional description of the product), provided it does not confuse or detract from the proper shipping name or other required information ! For fissile radionuclides, except Pu-238, Pu-239, and Pu-241, the weight in grams or kilograms may be used *in place of* activity units. For Pu-238, Pu-239, and Pu-241, the weight in grams or kilograms may optionally be entered *in addition to* activity units [see § 172.203(d)(4)] ! Emergency response hazards and guidance information (§§ 172.600-604) may be entered on the shipping papers, or may be carried with the shipping papers [§ 172.602(b)]

Some Special Considerations/Exceptions for Shipping Paper Requirements

! Shipments of Radioactive Material, excepted packages, under UN2910 (e.g., Limited Quantity, Empty packages, and Radioactive Instrument and Article), are excepted from shipping papers. For limited quantities (§173.421), this is only true if the limited quantity is not a hazardous substance (RQ) or hazardous waste (40 CFR 262).
! Shipping papers must be in the pocket on the left door, or readily visible to person entering driver's compartment and within arm's reach of the driver.
! For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, be designated by an "X" (or "RQ") in the hazardous material column, or be highlighted in a contrasting color.

Hazard Communications for Class 7 (Radioactive) Materials

Marking Packages (49 CFR 172.300-338)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Markings Always Required Unless Excepted	Additional Markings Sometimes Required	Optional Markings
Non-Bulk Packages ! Proper shipping name ! U.N. identification number ! Name and address of consignor or consignee, *unless*: (A) highway only and no motor carrier transfers, or B. part of carload or truckload lot or freight container load, and entire contents of railcar, truck, or freight container are shipped from one consignor to one consignee [see §172.301(d)] Bulk Packages (i.e., net capacity greater than 119 gallons as a receptacle for liquid, or 119 gallons and 882 pounds as a receptacle for solid, or water capacity greater than 1000 lbs, with no consideration of intermediate forms of containment) ! U.N. identification number, on orange, rectangular panel (see §172.332) – some exceptions exist	Materials-Based Requirements: ! If in excess of 110 lbs (50 kg), Gross Weight ! If non-bulk liquid package, underlined double arrows indicating upright orientation (two opposite sides) [ISO Std 780-1985 marking]  ! If a Hazardous substance in non-bulk package, the letters "RQ" in association with the proper shipping name Package-Based Requirements: ! The package type if Type A or Type B (½" or greater letters) ! The specification-required markings [e.g., for Spec. 7A packages: "DOT 7A Type A" and "Radioactive Material" (see §178.350-353)] ! For approved packages, the certificate ID number (e.g., USA/9166/B(U), USA/9150/B(U)-85, ...) ! If Type B, the trefoil (radiation) symbol per Part 172 App. B [*size*: outer radius ≥ 20 mm (0.8 in)] ! For NRC certified packages, the model number, gross weight, and package ID number (10 CFR 71.85) Administrative-Based Requirements: ! If a DOT exemption is being used, "DOT-E" followed by the exemption number ! If an export shipment, "USA" in conjunction with the specification markings or certificate markings	! "IP-1," "IP-2," or "IP-3" on industrial packaging is recommended ! Both the name and address of consignor and consignee are recommended ! Other markings (e.g., advertising) are permitted, but must be sufficiently away from required markings and labeling

Some Special Considerations/Exceptions for Marking Requirements

! Marking is required to be: (1) durable, (2) printed on a package, label, tag, or sign, (3) unobscured by labels or attachments, (4) isolated from other marks, and (5) be representative of the HAZMAT contents of the package.
! Limited Quantity (§173.421) packages and Articles Containing Natural Uranium and Thorium (§173.426) must bear the marking "radioactive" on the outside of the inner package or the outer package itself, and are excepted from other marking. The excepted packages shipped under UN 2910 must also have the accompanying statement that is required by §173.422.
! Empty (§173.428) and Radioactive Instrument and Article (§173.424) packages are excepted from marking.
! Shipment of LSA or SCO required by §173.427 to be consigned as exclusive use are excepted from marking except that the exterior of each non-bulk package must be marked "Radioactive-LSA" or "Radioactive-SCO," as appropriate. Examples of this category are domestic, strong-tight containers with less than an A_2 quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52.
! For bulk packages, marking may be required on more than one side of the package (see 49 CFR 172.302(a)).

Hazard Communications for Class 7 (Radioactive) Materials

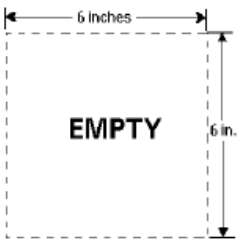
Labeling Packages (49 CFR 172.400-450)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Placement of Radioactive Labels

! Labeling is required to be: (1) placed near the required marking of the proper shipping name, (2) printed or affixed to the package surface (not the bottom), (3) in contrast with its background, (4) unobscured by markings or attachments, (5) within color, design, and size tolerance, and (6) representative of the HAZMAT contents of the package.
! For labeling of radioactive materials packages, two labels are required on opposite sides excluding the bottom.

Determination of Required Label

Size: *Sides:* ≥ 100 mm (3.9 in.) *Border:* 5-6.3 mm (0.2-0.25 in.)	 49 CFR 172.436	 49 CFR 172.438	 49 CFR 172.440	 49 CFR 172.450
Label	**WHITE-I**	**YELLOW-II**	**YELLOW-III**	**EMPTY LABEL**
Required when:	Surface radiation level < 0.005 mSv/hr (0.5 mrem/hr)	0.005 mSv/hr (0.5 mrem/hr) < surface radiation level ≤ 0.5 mSv/hr (50 mrem/hr)	0.5 mSv/hr (50 mrem/hr) < surface radiation level ≤ 2 mSv/hr (200 mrem/h) [*Note:* 10 mSv/hr (1000 mrem/hr) for exclusive-use closed vehicle (§173.441(b)]	The EMPTY label is required for shipments of empty Class 7 (radioactive) packages made pursuant to §173.428. It must cover any previous labels, or they must be removed or obliterated.
Or:	**TI = 0** [1 meter dose rate < 0.0005 mSv/hr (0.05 mrem/hr)]	**TI ≤ 1** [1 meter dose rate < 0.01 mSv/hr (1 mrem/hr)]	**TI ≤ 10** [1 meter dose rate < 0.1 mSv/hr (10 mrem/hr)] [*Note:* There is no *package* TI limit for exclusive-use]	
Notes:	! Any package containing a Highway Route Controlled Quantity (HRCQ) must bear a YELLOW-III label ! Although radiation level transport indices (TIs) are shown above, for fissile material, the TI is typically determined on the basis of criticality control			

Content on Radioactive Labels

! RADIOACTIVE Label must contain (entered using a durable, weather-resistant means):
(1) The radionuclides in the package (with consideration of available space). Symbols (e.g., Co-60) are acceptable
(2) The activity in SI units (e.g., Bq, TBq), or both SI units with customary units (e.g., Ci, mCi) in parenthesis. However, for domestic shipments, the activity *may* be expressed in terms of customary units only, until 4/1/97.
(3) The Transport Index (TI) in the supplied box. The TI is entered *only* on YELLOW-II and YELLOW-III labels.

Some Special Considerations/Exceptions for Labeling Requirements

! For materials meeting the definition of another hazard class, labels for each secondary hazard class need to be affixed to the package. The subsidiary label *may* not be required on opposite sides, and must not display the hazard class number
! Radioactive Material, excepted packages, under UN2910 (e.g., Limited Quantity, Empty packages, and Radioactive Instrument and Article), are excepted from labeling. However, if the excepted quantity meets the definition for another hazard class, it is re-classed for that hazard. Hazard communication requirements for the other class are required
! Labeling exceptions exist for shipment of LSA or SCO required by § 173.427 to be consigned as exclusive use
! The "Cargo Aircraft Only" label is typically required for radioactive materials packages shipped by air [§ 172.402(c)]

Hazard Communications for Class 7 (Radioactive) Materials

Placarding Vehicles (49 CFR 172.500-560)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Visibility and Display of Radioactive Placard

! Placards are required to be displayed:
- C. on four sides of the vehicle
- D. visible from the direction they face, (for the front side of trucks, tractor-front, trailer, or both are authorized)
- E. clear of appurtenances and devices (e.g., ladders, pipes, tarpaulins)
- F. at least 3 inches from any markings (such as advertisements) which may reduce placard's effectiveness
- G. upright and on-point such that the words read horizontally
- H. in contrast with the background, or have a lined-border which contrasts with the background
- I. such that dirt or water from the transport vehicle's wheels will not strike them
- J. securely attached or affixed to the vehicle, or in a holder.

! Placard must be maintained by carrier to keep color, legibility, and visibility.

Conditions Requiring Placarding

! Placards are required for any vehicle containing package with a RADIOACTIVE Yellow-III label.

! Placards are required for shipment of LSA or SCO required by §173.427 to be consigned as exclusive use. Examples of this category are domestic, strong-tight containers with less than an A_2 quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52. Also, for bulk packages of these materials, the orange panel *marking* with the UN Identification number is not required.

! Placards are required any vehicle containing package with a Highway Route Controlled Quantity (**HRCQ**). In this case, the placard must be placed in a square background as shown below (see §173.507(a)).

Radioactive Placard

Size Specs:			
Sides: ≥ 273 mm (10.8 in.) *Solid line Inner border:* About 12.7 mm (0.5 in.) from edges *Lettering:* ≥ 41 mm (1.6 in.) *Square for HRCQ:* 387mm (15.25 in.) outside length by 25.4 mm (1 in.) thick	 49 CFR 172.556	 IAEA SS 6 (1985) paras. 443-444	 See 49 CFR 172.527 AND 556
	RADIOACTIVE PLACARD (Domestic) *Base of yellow solid area:* 29 ± 5 mm (1.1 ± 0.2 in.) above horizontal centerline	**RADIOACTIVE PLACARD (International)**	**RADIOACTIVE PLACARD FOR HIGHWAY ROUTE CONTROLLED QUANTITY** (either domestic or international placard could be in middle)

Some Special Considerations/Exceptions for Placarding Requirements

! Domestically, substitution of the UN ID number for the word "RADIOACTIVE" on the placard is prohibited for Class 7 materials. However, some import shipments may have this substitution in accordance with international regulations.

! Bulk packages require the orange, rectangular panel marking containing the UN ID number, which must be placed adjacent to the placard (see §172.332) [*NOTE:* except for LSA/ SCO exclusive use under §173.427, as above].

! If placarding for more than one hazard class, subsidiary placards must not display the hazard class number. Uranium Hexafluoride (UF_6) shipments ≥ 454 kg (1001 lbs) require both RADIOACTIVE and CORROSIVE (Class 8) placarding.

! For shipments of radiography cameras in convenience overpacks, if the overpack does not require a RADIOACTIVE – YELLOW III label, vehicle placarding is not required (regardless of the label which must be placed on the camera).

Minimum Required Packaging For Class 7 (Radioactive) Materials

This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Quantity:	< 70 Bq/g (< 0.002 µCi/g)	Limited Quantity (§173.421)	A_1/A_2 value	1 rem/hr at 3 m, unshielded (§173.435)	(§173.427)

Non-LSA/SCO:	Excepted	Type A	Type B [3]	
Domestic or International LSA/SCO: LSA-I solid, (liquid)[1] SCO-I	Excepted	IP-I		Type B [3]
LSA-I Liquid LSA-II Solid, (liquid or gas)[1] (LSA-III)[1] SCO-II		IP-II		Type B [3]
LSA-II Liquid or Gas LSA-III		IP-III		Type B [3]
Domestic (only) LSA/SCO: LSA-I, II, III; SCO-I, II	Excepted	Strong-tight [2]	DOT Spec. 7A Type A	Type B [3] NRC Type A LSA [3,4]

1. For entries in parentheses, exclusive use is required for shipment in an IP (e.g., shipment of LSA-I liquid in an IP-I packaging would require exclusive use consignment)
2. Exclusive use required for strong-tight container shipments made pursuant to §173.427(b)(2)
3. Subject to conditions in Certificate, if NRC package
4. Exclusive use required, see §173.427(b)(4). Use of these packages expires on 4/1/99 (10 CFR 71.52)

Package and Vehicle Radiation Level Limits (49 CFR 173.441) [A]

This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Transport Vehicle Use:	Non-Exclusive	Exclusive		
Transport Vehicle Type:	Open or Closed	Open (flat-bed)	Open w/Enclosure [B]	Closed
Package (or freight container) **Limits:**				
External Surface	2 mSv/hr **(200 mrem/hr)**	2 mSv/hr **(200 mrem/hr)**	10 mSv/hr **(1000 mrem/hr)**	10 mSv/hr **(1000 mrem/hr)**
Transport Index (TI) [C]	10	no limit		
Roadway or Railway Vehicle (or freight container) **Limits:**				
Any point on the outer surface	N/A	N/A	N/A	2 mSv/hr **(200 mrem/hr)**
Vertical planes projected from outer edges		2 mSv/hr **(200 mrem/hr)**	2 mSv/hr **(200 mrem/hr)**	N/A
Top of . . .		load: **(200 mrem/hr)**	enclosure: 2 mSv/hr **(200 mrem/hr)**	vehicle: 2 mSv/hr **(200 mrem/hr)**
2 meters from. . .		vertical planes: 0.1 mSv/hr **(10 mrem/hr)**	vertical planes: 0.1 mSv/hr **(10 mrem/hr)**	outer lateral surfaces: 0.1 mSv/hr **(10 mrem/hr)**
Underside		2 mSv/hr **(200 mrem/hr)**		
Occupied position	N/A [D]	0.02 mSv/hr **(2 mrem/hr)** [E]		
Sum of package TI's	50	no limit [F]		

A. The limits in this table do not apply to excepted packages – see 49 CFR 173.421-426.
B. Securely attached (to vehicle), access-limiting enclosure; package personnel barriers are considered as enclosures.
C. For nonfissile radioactive materials packages, the dimensionless number equivalent to maximum radiation level at 1 m (3.3 feet) from the exterior package surface, in millirem/hour.
D. No dose limit is specified, but separation distances apply to Radioactive Yellow-II or Radioactive Yellow-III labeled packages.
E. Does not apply to private carrier wearing dosimetry if under Radiation Protection Program satisfying 10 CFR 20 or 49 CFR 172 Subpart I.
F. Some fissile shipments may have combined conveyance TI limit of 100 – see 10 CFR 71.59 and 49 CFR 173.457.

Package and Vehicle Contamination Limits (49 CFR 173.443)

This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

NOTE: All values for contamination in DOT rules are to be averaged over each 300 cm^2
Sufficient measurements must be taken in the appropriate locations to yield representative assessments

$\beta\gamma$ means the sum of beta emitters, gamma emitters, and low-toxicity alpha emitters
A means the sum of all other alpha emitters (i.e., other than low-toxicity alpha emitters)

The Basic Contamination Limits for All Packages: 49 CFR 173.443(a), Table 11	**General Requirement: Non-fixed (removable) contamination must be kept as low as reasonably achievable (ALARA)**
	$\beta\gamma$: 0.4 Bq/cm^2 = 40 Bq/100 cm^2 = $1x10^{-5}$ µCi/cm^2 = 2200 dpm/100 cm^2
	A: 0.04 Bq/cm^2 = 4 Bq/100 cm^2 = $1x10^{-6}$ µCi/cm^2 = 220 dpm/100 cm^2

The following exceptions and deviations from the above basic limits exist:

Deviation from Basic Limits	**Regulation 49 CFR §§**	**Applicable Location and Conditions Which must Be Met:**
10 times the basic limits	173.443(b) and 173.443(c) Also see 177.843 (highway)	On any external surface of a package in an exclusive use shipment, during transport including end of transport. Conditions include: (1) Contamination levels at beginning of transport must be below the basic limits. (2) Vehicle must not be returned to service until radiation level is shown to be ≤ 0.005 mSv/hr (0.5 mrem/hr) at any accessible surface, and there is no significant removable (non-fixed) contamination.
10 times the basic limits	173.443(d) Also see 177.843 (highway)	On any external surface of a package, at the beginning or end of transport, if a closed transport vehicle is used, solely for transporting radioactive materials packages. Conditions include: (1) A survey of the interior surfaces of the empty vehicle must show that the radiation level at any point does not exceed 0.1 mSv/hr (10 mrem/hr) at the surface, or 0.02 mSv/hr (2 mrem/hr) at 1 meter (3.3 ft). (2) Exterior of vehicle must be conspicuously stenciled, "For Radioactive Materials Use Only" in letters at least 76 mm (3 inches) high, on both sides. (3) Vehicle must be kept closed except when loading and unloading.
100 times the basic limits	173.428	**Internal** contamination limit for excepted package-empty packaging, Class 7 (Radioactive) Material, shipped in accordance with 49 CFR 173.428. Conditions include: (1) The basic contamination limits (above) apply to **external** surfaces of package. (2) Radiation level must be ≤ 0.005 mSv/hr (0.5 mrem/hr) at any external surface. (3) Notice in §173.422(a)(4) must accompany shipment. (4) Package is in unimpaired condition & securely closed to prevent leakage. (5) Labels are removed, obliterated, or covered, and the "empty" label (§172.450) is affixed to the package.

In addition, after any incident involving spillage, breakage, or suspected contamination, the modal-specific DOT regulations (§177.861(a), highway; §174.750(a), railway; and §175.700(b), air) specify that vehicles, buildings, areas, or equipment have "no significant removable surface contamination," before being returned to service or routinely occupied. The carrier must also notify offer or at the earliest practicable moment after incident.

Sample Certificate Enclose In, or On Package, Included with the Packing List, or Otherwise Forwarded With the Package

This package conforms to the conditions, and limitations specified in 49 CFR 173.424 for radioactive material, except package-instruments or articles, UN2910.

(*Signed*) Radiation Safety Officer

Appendix P

Waste Disposal

Waste Management Procedures

General Guidelines

- All radioactivity labels must be defaced or removed from containers and packages prior to disposal in ordinary (non-radioactive) waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
- Remind workers that non-radioactive waste such as leftover reagents, boxes, and packaging material should not be mixed with radioactive waste.
- Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
- In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and costs.
- Waste management program should include waste handling procedures for the users within their assigned areas, and for waste handlers who may collect waste from areas of use to bring to the storage area for eventual disposal.
- Housekeeping staff should be provided adequate training to avoid the possibility of unauthorized disposal or exposure of these individuals to radioactive materials or to radiation.

Procedure for Disposal by Decay-in-storage (DIS)

- Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.
- Short-lived waste should be segregated from long-lived waste (half-life greater than 120 days) at the source.
- Waste should be stored in suitable well-marked containers, and the containers should provide adequate shielding, and waste physical form should be compatible with the waste container.
- Liquid and solid wastes must be stored separately.
- When the container is full, it should be sealed. The sealed container should be identified with a label affixed or attached to it.
- The identification label should include the date when the container was sealed, the longest-lived radioisotope in the container, and the initials of the individual who sealed the container. The container may be transferred to the DIS area.
- The contents of the container should be allowed to decay for at least 10 half-lives of the longest-lived radioisotope in the container.
- Prior to disposal as ordinary trash, each container should be monitored as follows:
  - Check the radiation detection survey meter for proper operation;
  - Survey the contents of each container in a low background area;
  - Remove any shielding from around the container;
  - Monitor all surfaces of the container;
  - Discard the contents as ordinary trash only if the surveys of the contents indicate no residual radioactivity, i.e., surface readings are indistinguishable from background; and
  - If the surveys indicate residual radioactivity, return the container to DIS area and contact the RSO for further instructions.

- If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste (used or unused material, gloves, etc.), survey instrument used, and the initials of the individual performing surveys and disposing of the waste.

All radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash. Syringes/needles placed into sealed waste containers for decay do not need the labels removed provided that the following is done: waste barrels are sealed prior to delivery to the waste disposal firm and delivered directly from the licensee's facility; labels are removed from the waste barrels/containers; the waste is incinerated, not placed in a landfill; and the waste disposal firm is cautioned not to open the container prior to incineration.

Procedure for Disposal of Liquids Into Sanitary Sewerage

- Confirm that sewerage system is a public system, not a private sewerage system, septic system, or leach field.
- Confirm that the liquid waste being discharged is soluble or biological material that is readily dispersible in water.
- Calculate the amount of each radioisotope that can be discharged by using the information from prior, similar discharges and the information in **12VAC5-481-3690**.
- Make sure that the amount of each radioisotope does not exceed the monthly and annual discharge limits specified in **12VAC5-481-930** and **12VAC5-481-3690**.
- Record the date, radioisotope(s), estimated activity of each radioisotope, location where the material is discharged, and the initials of the individual discharging the waste.
- Liquid waste should be discharged only via designated sinks, toilets or release points.
- Discharge liquid waste slowly with water running from the faucet to dilute it.
- Survey the sink and surrounding work surfaces to confirm that no residual material or contamination remained in the sink or on work surfaces.
- Prior to leaving the area, decontaminate all areas or surfaces, if found to be contaminated.
- Maintain records of each radioisotope and its quantity and concentration that is released into the sanitary sewer system.

Procedure for Incineration

These guidelines apply to noncommercial waste disposal (i.e.; incineration of a licensee's own waste). You do not need specific VDH approval in order to incinerate certain categories of radioactive waste. For example, **12VAC5-481-950** provides that tritium and carbon-14 in low level concentrations, in liquid scintillation media and animal tissue, may be disposed of without regard to radioactivity. After you review your program and confirm that you have waste which required specific VDH approval for incineration, please provide the following information in your license application (**12VAC5-481-1060**).

- Describe the training and experience of the person who will be responsible for the on-site and day-to-day supervision of incinerator operations.
- Describe the waste that is proposed to be incinerated to include the chemical and/or physical form of the waste containing licensed material and a description of how the waste is segregated, packaged, and labeled for transfer from the generation site to the incinerator; the name of the radioisotope, concentration of radioactivity averaged over the weight of the material to be incinerated (microcuries per gram of waste medium) for each isotope to be incinerated; and the total radioactivity of each isotope per burn and the total number of burns per year. Describe procedures for ensuring that these frequencies and activities will not be exceeded.

- Describe the procedures for packaging, handling, securing, and monitoring of waste to prevent contamination and/or unnecessary exposure to personnel or property during the waste life cycle.
- Describe your method for measuring or estimating the concentration of radioactive material remaining in the ash residue. Describe your procedures for collection, handling, and disposal of ash residue.
- Describe the recordkeeping procedures for the waste incineration program. Records must be adequate to document all receipts, incineration, environmental releases of effluents, and any disposals of ash generated in the incineration process.
- Describe the characteristics of the incinerator and the site location including: height of the stack, rated air flow (cubic feet per hour or similar units); proximity of the stack or other discharge to occupied areas (e.g.; residences, school, hospital); and distance to the nearest air intake ducts of adjacent buildings. Describe any scrubbers, filters, or air cleaning equipment that is present.
- State how the concentration of radionuclides released, both as airborne effluent and as liquid effluent from scrubbers, condensers, or associated systems, will be measured or otherwise determined. Describe any stack monitoring that is planned.
- Provide a copy of the written safety analysis that demonstrates that the applicant will be able to incinerate the types and quantities of radioactivity specified in the application without exceeding the environmental release limits specified in **12VAC5-481,** 'Virginia Radiation Protection Regulations'**, Part IV,** 'Standards for Protection Against Radiation'.
- Provide a written commitment that the applicant has coordinated with the appropriate state and local authorities and that such permits and other authorizations as may be necessary to have been obtained.
- Provide a copy of the radiation safety procedures for monitoring personnel involved in incineration operations, and for monitoring all effluent generated by the incineration process. The procedures must ensure that VDH limits for environmental releases of radioactivity will not be exceeded. The applicant must describe how any ash generated exceeding VDH limits will be disposed of.

Procedure for Compaction

The following information should be provided by licensees who propose to compact waste (**12VAC5-481-1060**):

- Describe the compactor to demonstrate that it is adequately designed and manufactured to safely compact the type and quantity of waste generated during licensed operation (e.g., manufacturer's specifications, annotated sketches, photographs, etc.)
- Describe the type, quantity, and concentrations of waste to be compacted
- Provide an analysis of the potential for airborne release of radioactive material during compaction activities
- State the location of the compactor(s) within the waste processing area(s), as well as a description of the ventilation and filtering systems used in conjunction with the compactors. Include a description of the procedures for monitoring filter blockage and exchange
- Discuss the methods used to monitor worker breathing zones and/or exhaust systems
- Discuss the types and frequencies of surveys that will be performed for contamination control in the compactor area
- Discuss the instruction provided to compactor operators, including instructions for protective clothing, checks for proper functioning of equipment, method of handling uncompacted waste, and examining containers for defects.

Appendix Q

Medical Distribution

Medical Distribution

The purpose of this appendix is to provide assistance to the applicant or licensee in preparing applications for new licenses, license amendments, and renewals of medical distribution licenses (i.e., licenses that authorize the distribution of devices or sources to VDH, NRC and other agreement states' medical use licensees).

The medical distribution license only authorizes distribution; it does not authorize the possession of byproduct material. VAREG ORH-720 I, 'Guidance for Radiopharmacy Licenses' contains much of the information needed in preparing applications for medical distribution licenses. In order to avoid duplication, many sections in this appendix will refer you to VAREG ORH-720 I. Some applications for manufacture and distribution of radioactive drugs require a separate application. Nuclear pharmacy applicants should refer to VAREG ORH-720 I in the preparation of an application for transfer for distribution of radioactive drugs for medical use.

This appendix describes the application procedures to manufacture and distribute to medical use licensees and conduct research and development. Several words and phrases used in this guide should be explained. The term "distribution" has the same meaning as in **12VAC5-481-480**, i.e., the routine transfer of licensed materials to others. For organizations licensed in accordance with **12VAC5-481-480 I** and **J**, these transfers of licensed material are to specific licensees in accordance with the requirements of **12VAC5-481-570**; these organizations' principal customers are medical use licensees. The phrase "medical use licensee" means a physician, podiatrist, dentist, or medical institution licensed under **12VAC5-481, Part VII** for "medical use," as defined in **12VAC5-481-10**.

A request for an exemption from **12VAC5-481-480 I** should be made from broad scope research and development licensees who are requesting to manufacture and distribute drugs containing byproduct material, pursuant to **12VAC5-481-480 I**, to authorized recipients for human use research. An exemption may be granted if the applicant or licensee specifically requests an exemption from **12VAC5-481-480 I** and provides the following supporting information with regard to **12VAC5-481-480 I**:

- The applicant or licensee must confirm that *only* radioactive drugs for which the FDA has accepted an IND application containing microcurie quantities of hydrogen-3 or carbon-14 will be prepared and distributed. (The FDA, in **21 CFR 207.10(d)**, exempts classes of persons who manufacture or process drugs not for sale, but solely for use in research, teaching, and chemical analysis, from registering with the FDA as a drug manufacturer.)
- The applicant or licensee must confirm that it is not registered with Virginia or the FDA as a drug manufacturer.
- The applicant or licensee must confirm that it is not licensed as a pharmacy (in order to operate as such you would need to employ an Authorized Nuclear Pharmacist (ANP)). The risk imposed by the radioactive drugs containing only microcurie quantities of hydrogen-3 or carbon-14 does not warrant imposing the additional burden of hiring an ANP for the license. The applicant or licensee may also have proprietary concerns with hiring an ANP for short periods of time to work on the development of new drugs.
- The applicant or licensee must confirm that it is neither a nuclear pharmacy nor located within a federal institution.
- The applicant or licensee must agree to meet all other *applicable* sections of **12VAC5-481-480 I**.

If the exemption is granted, the following authorized use will be added to the license for Hydrogen-3 and Carbon-14:

- Preparation and distribution of radioactive drugs to authorized recipients in accordance with **12VAC5-481-480 I**.

In addition, the following license condition will be added to the license:

- Notwithstanding **12VAC5-481-480 I**, the licensee is authorized to prepare radioactive drugs in accordance with an accepted U.S. Food and Drug Administration (FDA) Investigational New Drug (IND) application protocol; and to distribute them to medical use licensees in accordance with **12VAC5-481-480 I**.

Since this exemption applies to broad scope research and development licensees, the broad scope licensee will not require an exemption from **12VAC5-481-470 E** which restricts broad scope licensees from adding byproduct material to drugs designed for human use when applying for **12VAC5-481-480 I** authorization. The addition of authorization to manufacture, prepare, or transfer radioactive drugs containing byproduct material for medical use (**12VAC5-481-480 I**) to a license authorizes **12VAC5-481-480** activities in addition to **12VAC5-481-470** (broad scope) activities. Preparation of radioactive drugs is done under the **12VAC5-481-480** authorization and not the **12VAC5-481-470** authorization.

CONTENTS OF AN APPLICATION

The following paragraphs are numbered as on the VDH form, 'Application for a Radioactive Material License Authorizing Manufacturing and Distribution,' (**Appendix A**).

Item 1 TYPE OF APPLICATION
See Item 1.

Item 2 NAME AND MAILING ADDRESS OF APPLICANT
See Item 2.

Item 3 PERSON TO BE CONTACTED REGARDING APPLICATION
See Item 3.

Item 4 ADDRESS(ES) WHERE RADIOACTIVE MATERIAL WILL BE USED OR POSSESSED
See Item 4.

Items 5 through 7 INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE; AUTHORIZED USERS; TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED ARES
See Item 5 through 7

Item 8 RADIOACTIVE MATERIALS

Identify the materials you wish to be authorized to distribute to medical use licensees. The regulatory requirements and the subsequent information that is needed are different for radioactive drug and for sealed source licenses. For radioactive drugs, specify the radionuclide and chemical form (for generators, specify the parent and daughter radionuclides and the name and model number, if appropriate, of the generator). For sealed sources, specify the radionuclide, manufacturer's name and model number of each source, the maximum activity in each source, total number of sources expected to be possessed at any one time, and the anticipated use of the sources. If the sealed sources are used in a device, specify the model number of the device.

The following examples show appropriate responses to Items 5 and 6.
Radioactive Drugs: Chromium-51 as Sodium Chromate
Molybdenum-99 as Molybdenum-99/Technetium-99m Generator (Model MTG-1)

Sealed Sources: I-125, XYZ Corp., Model 1234
Maximum activity per source: Ci
Total activity possessed: Ci
To be used by medical use licensees authorized for use in **12VAC5-481-2010**.

Pd-103, XYZ Corp., Model 1234
Maximum activity per source: Ci
Total activity possessed: Ci
To be used by medical use licensees authorized for use in **12VAC5-481-2010**.

Ir-192, XYZ Corp., Model 1234
Maximum activity per source: Ci
Total activity possessed: Ci
For manufacturer, distribution and service of (device name) model number XXX to be used by medical use licensees authorized for use in **12VAC5-481-2040**.

Item 9 FACILITIES AND EQUIPMENT
See Item 9

Item 10 RADIATION SAFETY PROGRAM
According to **12VAC5-481-480 I** and **J**, certain radiation safety information must be submitted regarding licensed material to be distributed to medical use licensees. The information to be submitted for each type of licensed material to be distributed to medical use licensees is identified in the following sections and in VAREG ORH-720 I, 'Guidance for Radiopharmacy Licenses.'

Note: The numbered items listed below for **Item 10** no longer reflect the numbered items as listed on the VDH form, 'Application for Application for a Radioactive Material License Authorizing Manufacturing and Distribution,' (**Appendix A**).

Item 10.1 Radioactive Drugs
If you wish to distribute radioactive drugs to medical use licensees pursuant to **12VAC5-481-1900, 12VAC5-481-1920**, and **12VAC5-481-1950**, you need to provide the information identified below or in VAREG ORH-720 I, 'Guidance for Radiopharmacy Licenses,' for nuclear pharmacy license applicants.

Item 10.1.1 Radioactive Drugs – Commercial Distribution
According to **12VAC5-481-480 I**, you must provide evidence that you are registered or licensed with either the U.S. Food and Drug Administration (FDA) or a state agency as a drug manufacturer. See VAREG ORH-720 I, 'Guidance for Radiopharmacy Licenses,' for nuclear pharmacy license applicants.

Item 10.1.2 Radioactive Drugs – Instrumentation
According to **12VAC5-481-480 I**, you must possess and use instrumentation to measure the radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. Measurements may be made by direct measurement or a combination of direct measurement and calculation (calculation only may be used for alpha and beta radiation). See VAREG ORH-720 I, 'Guidance for Radiopharmacy Licenses' for nuclear pharmacy license applicants.

Item 10.1.3 Radioactive Drugs – Packaging and Shielding Licensing Criteria
See VAREG ORH-720 I, 'Guidance for Radiopharmacy Licenses'.

Item 10.1.4 Radioactive Drugs – Licensing Criteria for Labeling
See VAREG ORH-720 I, 'Guidance for Radiopharmacy Licenses'.

Item 10.1.5 Generators – Return Program
If you do not plan to offer a generator return program, so state. Some licensees offer a generator return program. In this program, customers may return used or spent generators to the licensee. Experience has shown that customers who do not ship radioactive materials frequently may not be familiar with the DOT regulations governing such shipments; the manufacturer's or distributor's instructions to customers have not been sufficiently detailed for these inexperienced shippers. As a result, when some spent generators were shipped back to the manufacturer or distributor, the shipment was not in accordance with applicable regulations.

Item 10.1.5.1 Licensing Criteria
If you do not plan to offer a generator return program, so state. If you wish to offer a generator return program, the instructions (including instructions on labeling and shipping documents) developed will have to be supplied to your customers and should be sufficiently detailed to ensure that the shipper can comply with **12VAC5-481-2980** and other appropriate DOT regulations. As a minimum, these instructions are to:

- Establish the user's responsibility and liability as the shipper;
- Provide step-by-step instructions for completing each item on each form and label that is involved in the shipping process; and
- Discuss all the customer's responsibilities as a shipper under **49 CFR Parts 170 to 189**.

Item 10.1.5.2 Return Program Procedures
If you do not plan to offer a generator return program, so state; no additional information is necessary. However, if you plan to offer a generator return program, copies or facsimiles of all forms, labels, and instructions you will provide to customers for shipping the spent generators back to your facility should be provided. To avoid the problems experienced in the past by inexperienced shippers, you should ensure that your instructions achieve the objectives outlined above. The discussion of the customer's responsibilities mentioned above should include (but is not limited to):

- The requirements for surveying and wipe-testing the packages;
- The distance at which to survey packages;
- The action levels for the package wipe-test results;
- The dose rate limitations on the particular shipping label that you provide; and
- The need for sealing tape or another mechanism to fulfill the security seal (tamper-indicating) requirement.

Item 10.2 Sealed Sources
If you intend to distribute sealed sources to medical use licensees, provide the information identified in VAREG ORH-720 I, 'Guidance for Radiopharmacy Licenses'.

Item 10.2.1 Sealed Sources in Devices – Licensing Criteria for Evaluation of Design and Construction
If you are a manufacturer or initial distributor of sealed sources (or devices containing sealed sources), you may need to submit a separate application for authorization to distribute the sealed sources or devices. To submit a source or device design for a safety evaluation and registration, use NUREG-1556, Vol. 3, "*Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration*." This safety evaluation is required by **12VAC5-481-480 J** prior to the source or device being approved for distribution and medical use.

Item 10.2.2 Sealed Sources – Labeling

Item 10.2.2.1 Licensing Criteria

Your product labeling must fulfill the requirements of **12VAC5-481-850, 12VAC5-481-880, 12VAC5-481-890** and of **12VAC5-481-480 J**.

A label, leaflet, or brochure accompanying the sealed source or device must contain appropriate instructions from a radiation safety standpoint for handling and storing the source or device. For example, the instructions may specify the use of extremity monitors, the use of tongs or other devices (rather than bare hands) to pick up sources, storage within auxiliary shielding, and any special procedures needed in the handling and sterilizing of "*fragile*" sources (e.g., iodine-125 seeds). A label, leaflet, or brochure must also contain the licensing statement required by **12VAC5-481-480 J**. For sources, the statement should read, "*The (name of source or device) is licensed by the Virginia Department of Health for distribution to persons licensed pursuant to [**12VAC5-481-1800, 12VAC5-481-2010**, or **12VAC5-481-2020**] or under equivalent licenses of the NRC or another Agreement State*."

For *each* type of sealed source or device you intend to distribute, you should:

- Submit copies or facsimiles of the labels that will accompany the product and specify where each label will be placed (e.g., on the device, on the source shield); and
- Submit copies of all leaflets and brochures that will accompany the product.

For *each* type of source or device to be distributed, you should provide a copy of correspondence to and from the FDA that clearly shows that the FDA finds the source or device to be safe and effective or "*substantially equivalent*" to sources or devices offered for sale in the United States before May 1976.

Devices and sources used in conjunction with medical applications involving computers and patient planning systems are within FDA jurisdiction and must also have a substantially equivalent letter pursuant to Section 510(k) of the Food, Drug, and Cosmetic Act, as amended, or a similar indication of premarketing approval by FDA.

Item 10.2.2.2 FDA Coordination

FDA and NRC signed a Memorandum of Understanding on August 26, 1993, to coordinate existing FDA and NRC regulatory programs for medical devices, drugs, and biological products that make use of byproduct, source, or special nuclear materials. The principal statute under which the FDA regulates devices is the Food, Drug, and Cosmetic Act, as amended by the Safe Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Medical Devices Act of 1992.

Under the Memorandum of Understanding, the agencies agree to promptly inform each other whenever they receive a report or otherwise become aware of potential public health problems involving products of mutual regulatory concern. Further, the agencies will share information to the extent practicable.

Item 10.2.3 Sealed Sources – Return Program and Device Service

Item 10.2.3.1 Experience with Returns

Some licensees offer a source return program or a device service or both. In this program, customers may return unused sources for credit or may return used sources or devices for disposal, service, or replacement. Similar programs have been offered by manufacturers of other products. Experience with these other products indicates that customers who do not ship radioactive materials frequently are often not familiar with Department of Transportation (DOT) regulations governing such shipments. Unless the manufacturer's or distributor's instructions to customers were sufficiently detailed for these inexperienced shippers, some shipments were not in accordance with applicable regulations. Similar problems may arise with sealed sources or devices that are being returned.

Item 10.2.3.2 Licensing Criteria
If you do not plan to offer a source return program or device service, so state; no additional information is necessary. However, if you offer a source return program or device service, you must have developed, and must supply to your customers, sufficiently detailed instructions (including instructions on labeling and shipping documents) to ensure that the shipper can comply with **12VAC5-481-2980** and appropriate DOT regulations.

You must also submit to VDH copies or facsimiles of all forms, labels, and instructions that you will provide to customers for shipping sources back to your facility. As a minimum, the instructions must:

- Establish the user's responsibility and liability as the shipper;
- Provide step-by-step instructions for completing each item on each form and label that is involved in the shipping process; and
- Discuss all the customer's responsibilities as a shipper under **49 CFR Parts 170 to 189**. This discussion of the customer's responsibilities should include (but is not limited to):
  - The requirements to survey and wipe-test packages;
  - The distance at which to survey packages;
  - The action levels for the package wipe-test results;
  - The dose rate limitations on the particular shipping label that you will provide; and
  - The need for sealing tape or another mechanism to fulfill the security seal requirement.

Item 10.2.4 Calibration or Reference Sources For Medical Use – Compatibility with 12VAC5-481-1800 Licensing Criteria
You must request authorization to distribute calibration or reference sources that are described in **12VAC5-481-1800**. These calibration or reference sources must not exceed the activity limits of **12VAC5-481-1800**, and according to **12VAC5-481-480 J**, you must confirm this in your license application. If a source to be distributed contains byproduct material exceeding the activity limits of **12VAC5-481-1800**, source material, or special nuclear materials, it may not be distributed to medical licensees under the provisions of **12VAC5-481-1800**. In such cases, medical use licensees may purchase such sources only if their licenses specifically authorize possession and use of them.

TERMINATION OF ACTIVITIES
See Item 10.13.
The distribution only license does not authorize the possession and use of byproduct material. Therefore, termination of your license only requires a letter notifying VDH of the termination. If you are also terminating your possession license, **12VAC5-481-500** requires that a licensee notify VDH promptly and request termination of the license. This notification normally requires:

- a completed 'Certificate of Disposition of Materials' (**Appendix B**) certifying that all sources have been disposed of properly; and
- the results of a final radiation survey of the premises where the licensed activities were carried out.

Item 11 FEES
See Item 11.

Item 12 CERTIFICATION
See Item 12.