Commonwealth of Virginia
Radiation Protection Regulatory Guide

Guidance for Licenses of Broad Scope

ORH-720 H

Virginia Department of Health
Radiological Health Program
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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 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 safety program meets the current rule and protects public health and safety.

Comments and suggestions for improvements in this VAREG are encouraged at all times 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 Licenses of Broad Scope' has been developed to streamline the application process for a Broad Scope License. A copy of the VDH Form 'Application for Radioactive Material License for Broad Scope' is located in **Appendix A** of this guide.

Appendix C through V provides 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** for a Broad Scope license.

In summary, the applicant will need to do the following to submit an application for a Broad Scope license:

- Use this regulatory guide to prepare the VDH Form, 'Application for Radioactive Material License for Broad Scope' (**Appendix A**).
- Complete the application VDH Form 'Application for Radioactive Material License for Broad Scope' (**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

ALI	annual limit on intake
ALARA	as low as is reasonably achievable
ANSI	American National Standards Institute
bkg	background
Bq	Becquerel
cc	centimeter cubed
CFR	Code of Federal Regulations
cm^2	centimeter squared
cpm	counts per minute
Ci	Curie
DFP	Decommissioning Funding Plan
DIS	decay-in-storage
DOE	United States Department of Energy
DOT	United States Department of Transportation
dpm	disintegrations per minute
EPA	United States Environmental Protection Agency
GBq	Gigabecquerel
GM	Geiger-Mueller
GPO	Government Printing Office
IAEA	International Atomic Energy Agency
IN	Information Notice
kBq	Kilobecquerel
LLW	Low Level Radioactive Waste
MBq	Megabequerel
µCi	Microcurie
mCi	Millicuries
mR	Milliroentgen
mrem	Millirem
mSv	Millisievert
NIST	National Institute of Standards and Technology
NMSS	NRC Office of Nuclear Material Safety and Safeguards
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OSL	optically stimulated luminescene dosimeters
R	Roentgen
RG	Regulatory Guide
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
SI	International System of Units (abbreviated SI from the French Le Systeme Internationale d'Unites)
SSDR	Sealed Source and Device Registration
Sv	Sievert
TEDE	Total Effective Dose Equivalent
TLD	thermoluminescent dosimeters
VDH	Virginia Department of Health
µCi	Microcurie

PURPOSE OF GUIDE

This document provides guidance to an applicant in preparing a broad scope license application and describes the criteria used by VDH staff when evaluating the application. An applicant for a limited scope license generally must submit to the VDH, for review and approval, the specific training and experience of each proposed user and the facilities and equipment available to support each proposed use; an applicant for a broad scope license normally must submit to the VDH, for review and approval, a description of the internal review process and criteria that will be used to approve users and uses. As opposed to limited scope licenses, which typically identify specific isotopes that may be possessed, the broad scope license generally authorizes the possession and use of a wide range of radioactive materials.

Because VDH grants significant decision making authority to broad scope licensees through the license, a broad scope license is not normally issued to a new licensee. An applicant for a broad scope license typically has several years of experience operating under a limited scope license and a good regulatory performance history. This document is intended to provide the additional guidance required by the experienced limited scope licensee to prepare an application for a broad scope license. Guidance related to specific program areas, which may not apply to all broad scope licensees, is not included in this document but can be found in other volumes of VAREGs or in guidance documents that have not yet undergone the consolidation process.

Applicants are expected to have first established limited scope licensed programs in accordance with the guidance described in the appropriate VAREG and then use this document to complete the application for broad scope license. For example, applicants for a broad scope license who use radioactive material for research and development should review VAREG ORH-720 F, ‘Guidance For Academic, Research and Development, and Other Licenses of Limited Scope’, for guidance. Similarly, applicants for broad scope license who use radioactive material for medical purposes should review VAREG ORH-720 G**, ‘**Guidance For Medical Use of Radioactive Material’.

12VAC5-481-470, "*Special requirements for specific licenses of broad scope*", provides for and defines three distinct categories of broad scope license: Type A, Type B, and Type C.

Type A licenses of broad scope are typically the largest licensed programs and encompass a broad range of uses. Type A broad scope licensees use a Radiation Safety Committee (RSC), Radiation Safety Officer (RSO), and criteria developed and submitted by the licensee and approved by VDH during the licensing process, to review and approve all uses and users under the license. The requirements for issuance of a Type A broad scope license are described in **12VAC5-481-470**. An applicant for a Type A broad scope license must establish administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control, and accounting and management review that are necessary to assure safe operations, including:

- Establishment of a RSC
- Appointment of a qualified RSO
- Establishment of appropriate administrative procedures to assure:
  -control of procurement and use of radioactive material;
  -completion of safety evaluations of proposed uses that take into consideration adequacy of facilities and equipment, training and experience of the user, and operating and handling procedures; and
  -review, approval, and recording by the RSC of safety evaluations of proposed uses.

Type B broad scope licensed programs are normally smaller and less diverse than Type A broad scope programs. Type B broad scope licensees use an RSO and criteria developed and submitted by the licensee and approved by VDH during the licensing process, to review and approve all uses and users under the license. Because the RSO reviews and approves all uses and users under the license, and not a full RSC as established for Type A broad scope programs, the types and quantities of radioactive material authorized by the Type B broad scope license are limited to those described in **12VAC5-481-470** and **12VAC5-481-3760.** While the quantities of individual radionuclides described in **12VAC5-481-3760** may be large, total license possession limits are further restricted by the Unity Rule (see **Item 9** for additional information on license possession limits and the Unity Rule). Generally, the scope of authorization for Type B licenses is limited to the experience and knowledge of the RSO. The requirements for issuance of a Type B broad scope license are described in **12VAC5-481-470**.

An applicant for a Type B broad scope license must also establish administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control, and accounting and management review that are necessary to assure safe operations, including:

- Appointment of a qualified RSO

- Establishment of appropriate administrative procedures to assure:
  -control of procurement and use of radioactive material;
  -completion of safety evaluations of proposed uses that take into consideration adequacy of facilities and equipment, training and experience of the user, and operating and handling procedures; and
  -review, approval, and recording by the RSO of safety evaluations of proposed uses.

Type C broad scope licensed programs are typically issued to institutions that do not require significant quantities of radioactive material but need the flexibility to possess a variety of different radioactive materials. Users of licensed material under these programs are approved by the licensee based on training and experience criteria described in **12VAC5-481-470**. The types and quantities of radioactive material authorized by the Type C broad scope license are limited to those described in **12VAC5-481-470** and **12VAC5-481-3760,** again, considering the Unity Rule. The requirements for issuance of a Type C broad scope license are described in **12VAC5-481-470.** While **12VAC5-481-470** does not require Type C broad scope licensees to appoint an RSO, the licensee must establish administrative controls and provisions relating to procurement of radioactive material, procedures, recordkeeping, material control and accounting, and management review to assure safe operations. This should include the appointment of someone responsible for the day-to-day operation of the radiation safety program, such as an RSO.

Except for activities specifically excluded from broad scope licenses by **12VAC5-481-470**, a Type A broad scope license can include any licensed material the applicant needs and for which it qualifies. An application for a Type A broad scope license can include uses of source material and special nuclear material under the same program (e.g., laboratory-scale research and development or the use of uranium as shielding) as the radioactive material to be possessed under the provisions of **12VAC5-481-440**. However, applicants should submit separate applications for the use of source and special nuclear materials for purposes not directly related to the use of radioactive material under the Type A broad scope license (e.g., use of source material in subcritical assemblies and special nuclear material in cardiac pacemakers).

Types B and C broad scope licenses are restricted in their possession of radioactive material by **12VAC5-481-470** and **12VAC5-481-3760.** Type B and Type C licensees who require materials not specified in **12VAC5-481-3760** will need to: (1) develop Type A broad scope programs, which would require a

license amendment; or (2) carry these additional materials under a separate specific license of limited scope. The latter option would require that the licensee review the appropriate VAREG related to the specific use of this material and submit the information required by the license reviewer as described in that document. For example, applicants who require materials not specified in **12VAC5-481-3760** for the purposes of research and development should review VAREG ORH-720 F, 'Guidance For Academic, Research and Development, and Other Licenses of Limited Scope' and submit the information described therein. Licensees are reminded that changes to the specific license of limited scope require amendment of the license.

Type B licensees who require quantities of material specified in **12VAC5-481-3760**, but in excess of that prescribed by **12VAC5-481-470**, will need to: (1) develop a Type A broad scope program; or (2) carry these additional materials under a separate specific license of limited scope, as described in the previous paragraph. Type C licensees who require quantities of material specified in **12VAC5-481-3760**, but in excess of that prescribed by **12VAC5-481-470**, will need to: (1) develop, as appropriate, a Type A or Type B broad scope program; or (2) carry these additional materials under a specific license of limited scope. Once again, changes to the specific license of limited scope require amendment of the license.

In practice, **12VAC5-481-470** reduces the administrative burden for both licensees and VDH without reducing the safety standards or lessening the licensing requirements for training, experience, facilities, and equipment. Both VDH and the licensee benefit from the reduction in license amendments that might otherwise be needed to change authorized radionuclides, quantities, or names of individuals who may use, or supervise the use of, radioactive material. **12VAC5-481-470** does not specifically permit a broad scope licensee to make other types of changes to the radiation safety program as described in the application. However, VDH has permitted broad scope licensees, on a case by case basis, to build in limited program flexibility during the licensing process. VDH will continue to allow licensees to build in this type of program flexibility.

Through license condition, VDH will provide even greater flexibility to Type A broad scope licensees who have developed an adequate radiation safety program oversight structure. Type A broad scope licensees and applicants for Type A broad scope license who specify the duties and responsibilities of management, the RSC, and the RSO, including: (1) review and approval of program and procedural

changes by the RSC; (2) implementation of program and procedural changes; (3) audit of licensed operations to determine compliance; and (4) taking appropriate actions when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence, will be authorized, through use of the license condition listed below, to make some program changes and to revise some procedures previously approved by VDH without amendment of the license as long as the program change or revised procedure:

- Is reviewed and approved by the RSC prior to implementation;
- Satisfies regulatory requirements;
- Does not change existing license conditions; and
- Does not decrease the effectiveness of the radiation safety program.

For Type A broad scope applicants or licensees requesting this additional flexibility, a clear description of the process for procedure and program review and approval must be provided. Applicants must describe how specific changes will be documented. At a minimum, documentation shall state the reason for the change and summarize the radiation safety matters that were considered prior to the approval of each change.

Example of a Type A Broad Scope License Condition used to grant additional flexibility:

- Notwithstanding the requirements of License Condition Number (insert number of license condition that incorporates the licensee's application and letters into the document), the licensee is authorized to make program changes and changes to procedures specifically identified in the (application dated or letter dated), which were previously approved by the agency and incorporated into the license, without prior VDH approval, as long as:

  -The proposed revision is documented, reviewed, and approved by the licensee's Radiation Safety Committee in accordance with established procedures prior to implementation;

  -The revised program is in accordance with **12VAC5-481 'Virginia Radiation Protection Regulations'**, will not change license conditions, and will not decrease the effectiveness of the radiation safety program;

  -The licensees staff is trained in the revised procedures prior to implementation; and

  -The licensees audit program evaluates the effectiveness of the change and its implementation.

The guidance that follows in this volume specifies that Type A broad scope licensees who have developed an adequate radiation safety program oversight structure may be granted the flexibility to make program changes and revise procedures in the areas of:

- Training for Individuals Working in or Frequenting Restricted Areas **(Item 8)**
- Audit Program **(Item 12.1)**
- Radiation Monitoring Instruments **(Item 12.2)**
- Material Receipt and Accountability **(Item 12.3)**
- Safe Use of Radionuclides and Emergency Procedures **(Item 12.6)**
- Surveys **(Item 12.8)**

This VAREG identifies the information needed to complete VDH Form, 'Application for Radioactive Material License for Broad Scope' (**Appendix A**), for the use of radioactive material for licenses of broad scope.

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

- **Rule** -- references the requirements of **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 the Commonwealth of Virginia according to VDH'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 be made when necessary. 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 safety 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,** 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 Radioactive Material License for Broad Scope’. VDH expects licensees to provide requested information on specific aspects of their proposed radiation safety program in attachments to the application. When necessary, VDH may ask the applicant for additional information to gain reasonable assurance that an adequate radiation safety 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 safety 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 safety 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 FACILITIES IN THE COMMONWEALTH OF VIRGINIA?

In the special situation of work at federally controlled sites in the 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. The 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 regulation 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 (see map on next page), 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 safety 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 must sign the submitted application acknowledging management's commitments and responsibility for all the following:

- Radiation safety, security and control of radioactive materials, and compliance with rule**;**
- Knowledge about the contents of the license and 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 safety program to ensure that public, and workers are protected from radiation hazards;
- Appointment of a qualified individual who has agreed in writing to work as the 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 J**.

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 the use of licensed material by broad scope licensees:

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

The following parts of **12VAC5-481 'Virginia Radiation Protection Regulations'** contain requirements which, depending on the type or types of activities authorized by the license, may be applicable to the use of licensed material by broad scope licensees:

- Part V "Radiation Safety Requirements for Industrial Radiographic Operations"
- Part VII "Use of Radionuclides in the Healing Arts"
- Part XII "Licensing and Radiation Safety Requirements for Irradiators"
- Part XIV "Radiation Safety Requirements for Wireline Service Operations and Subsurface Tracer Studies"

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 for Broad Scope' (**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 via 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 the 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, Virginia 23219

LICENSE FEES

The appropriate fee must accompany each application. Refer to **12VAC5-490** to determine the amount of the fee. VDH will not issue the new license prior to fee receipt. Once the application 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 15** of VDH Form, 'Application for Radioactive Material License for Broad Scope' (**Appendix A**) to: Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, Virginia 23219 or (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 appropriate, 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 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 immediately in the event of change of ownership or control and bankruptcy proceedings; see below for more details.

Timely Notification of Change of Ownership or 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 H identifies the information to be provided about changes of ownership or 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 compliance with 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 entities involved (e.g., trustees) so that health and safety issues can be resolved before bankruptcy actions are completed.

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

Reference: Copies of NRC Information Notices and NUREGs including: NRC's Policy and Guidance Directive PG 8-11, 'NMSS Procedures for Reviewing Declarations of Bankruptcy,' dated August 8, 1996, and NRC's Inspection Procedure 87103, 'Inspection of Material Licensee Involved in an Incident or Bankruptcy Filing' can be accessed at NRC's web site, http://www.nrc.gov.

Item 3: Person to Contact 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, 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 VDH 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 Licensed 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 or stored.

Applicants should identify the location of all facilities designed or established for special uses; e.g., panoramic irradiators, interim or long-term waste storage facilities, high activity laboratories, iodination facilities, alpha laboratories, incinerators, and animal facilities (see **Item 11** for further guidance).

Discussion: Specify each proposed location of use by the street address, city, and state or other descriptive address (such as on Highway 58, 5 miles east of the intersection of Highway 58 and State Route 16, Anytown, VA). The descriptive address should be sufficient to allow a VDH inspector to find the facility location. A Post Office box address is not acceptable.

If radioactive material is to be used at more than one location, give the specific address of each location. Applicants for a broad scope license need not identify each facility at a particular address where radioactive material will be used. For example, applicants can specify that radioactive material will be used on the Main Campus of ABC University located in Anytown, VA.

If radioactive material (e.g., portable gauging devices) will be used at temporary job sites, check the box requesting this authorization and describe the scope of these activities. If radioactive material is to be used in field studies, the activities must be specifically identified and authorized on the license. **Appendix I** contains information required of applicants prior to granting authorization for field use of licensed material.

A VDH-approved license amendment identifying a new location of 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).

Note: As discussed later in **Item 10 '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, written descriptions of the specific locations, or room numbers where licensed material is used or stored and any records of spills or other unusual occurrences involving the spread of contamination in or around the licensee's facilities.

Individual(s) Responsible for Radiation Safety Program

Item 5: Executive Management

Rule: 12VAC5-481-470, 12VAC5-481-630

Criteria: The applicant must have administrative controls and provisions relating to organization and management and management review necessary to assure safe operations.

Discussion: Executive management is the individual at the senior management level who is responsible for oversight of the radiation safety program and has the ultimate responsibility for the license and the activities associated with the license. Executive management has an important role in implementing and managing the radiation safety program. VDH expects executive management to be knowledgeable of the program.

Due to the various structures of different organizations, VDH recognizes that executive management may need to delegate certain responsibilities to other managers for the day-to-day oversight of the program. For example, a large company may have several licenses issued to it for different facilities or for different activities. In this case, a company may choose to establish a senior level manager with responsibility for all of the licenses issued to that company, with the day-to-day responsibility for each license designated to the facility senior manager or program area senior manager. There are numerous ways in which an applicant may wish to structure its management oversight to meet the needs of the organization. However, there must still be one level of management, as the licensee's representative, with ultimate responsibility for the radiation safety program.

In a Type A broad scope program, executive management or her/his delegate is a vital member of the Radiation Safety Committee (RSC) and should attend Committee meetings.

In all licensed programs, executive management should be knowledgeable of the results of periodic audits and the annual review of the licensed program, to ensure all activities are in compliance with regulatory requirements and the conditions of the license, and that activities are being conducted in a safe manner. Annual reviews and audits are discussed in more detail in **Item 12, 'Audit Program'**, of this guidance document.

The licensee should consider several factors when selecting executive management for the radiation safety program. This individual represents the highest level of facility management and has the authority to delegate resources for the program and appropriate funds in a timely manner. This individual must be available to facilitate effective and immediate action on behalf of management, the RSC (for Type A broad scope programs), and the RSO, particularly in the event of an emergency. Executive management must have the authority to make prompt decisions without having to consult with higher management officials, including the authority to take whatever action is necessary to ensure that all radiation safety practices are in accordance with the rules and conditions of the license.

Executive management is involved in selecting the chairperson and members of the RSC (for Type A broad scope) and the RSO (for Type A and Type B broad scope), and defines the role, duties and responsibilities of each. Executive management should support the RSC and the RSO, creating an atmosphere of cooperation and professionalism such that individuals feel comfortable raising radiation safety concerns. Authority will be enhanced if authorized users clearly understand that there is strong management support for, and participation in, the licensed program. Many problems can be avoided if management takes proactive steps before radiation safety problems escalate. Individuals should understand management's expectations regarding internal enforcement of program requirements and the consequences for non-compliance.

NRC NUREG-1516, "*Management of Radioactive Material Safety Programs at Medical Facilities*", Chapter 1, describes the role of executive management at medical facilities, but it also contains information pertinent to all broad scope programs.

Item 6: Radiation Safety Committee (RSC)

Rule: 12VAC5-481-470

Criteria: Type A broad scope licensees must establish a Radiation Safety Committee (RSC), which works with executive management and the Radiation Safety Officer (RSO) in implementing the radiation safety program. Type B and Type C broad scope licensees are not required to establish an RSC.

Discussion: An applicant for a Type A broad scope license must establish a RSC pursuant to **12VAC5-481-470**. The RSC works with executive management and the RSO in implementing the radiation safety program and will be involved in establishing policies and procedures for managing the radiation safety program. The RSC, through the executive management, must have the authority and flexibility necessary so that it may effectively fulfill its role in managing the radiation safety program.

The RSC for a Type A broad scope program is composed of such persons as the RSO, executive management, and persons trained and experienced in the safe use of radioactive materials. Each area of use under the license should be represented on the RSC.

A chairperson for the committee should be selected. There are several factors to consider when selecting a chairperson for the RSC. An individual with a knowledge of radiation safety issues, good leadership abilities, the authority and credibility by virtue of their position within the facility, and a desire to serve as chairperson will facilitate the effectiveness of the RSC. Additionally, the individual chosen as the chairperson must have the time to devote to the position in addition to other responsibilities he or she might have within the facility. Executive management should delegate a level of authority to the position so that the chairperson is effective. In general, the RSO should not be appointed as the chairperson of the Committee, since the RSO is responsible for the day-to-day operation of the radiation safety program and may be too closely involved with the licensed activities to be objective.

The RSC should establish a quorum for RSC meetings. A quorum consisting of the chairperson of the committee (or his/her designee), the RSO, the executive management (or his/her alternate), a representative from each area of use from which specific issues will be discussed, and any other member whose field of expertise is necessary for the discussion is considered acceptable.

The meeting frequency of RSC meetings for broad scope programs is not specified in **12VAC5-481-470**. The RSC should meet as often as needed to ensure the radiation safety program is operating in compliance with the license, established procedures, and the rule. For most programs, quarterly RSC meetings are needed to adequately oversee the program.

The RSC should maintain minutes of its meetings. The minutes should include the date of the meeting, the members present and absent to demonstrate a quorum was present, a summary of the discussions, recommendations and the results of votes. The RSC should also document its review of new users, uses, and program changes. The minutes should also include information related to the ALARA program reviews and the annual audit review.

Duties and Responsibilities

The committee is responsible for reviewing personnel dosimetry data, discussing the results of required radiation surveys, and any significant incidents, including spills, contamination, medical events, etc. The RSC is also required to review the program for maintaining doses ALARA and providing any necessary recommendations to ensure doses are ALARA. The overall compliance status for authorized users should be thoroughly reviewed. The RSC, working with the executive management, shares responsibility with the RSO for conducting periodic audits of the radiation safety program. Additionally, the RSC reviews any consultant's audit findings and acts upon those findings. The RSC also reviews the results of the annual audit of the radiation safety program. Possible trends should be analyzed and suggestions for timely and corrective action should be made. Problems should be clearly defined and reviewed in the future as open items. An assessment of the effectiveness of corrective actions is also helpful in deterring or eliminating future problems and violations.

One of the primary responsibilities of the RSC for a broad scope program is to evaluate new users and new uses of radioactive material. The RSC needs to consider all available information in making decisions. This includes evaluating the training and experience of applicants who request authorization to use radioactive material at the facility, using criteria developed by the RSC. The RSC members should be aware of the regulatory training and experience criteria that apply to each type of use at their institution. For example, **12VAC5-481 'Virginia Radiation Protection Regulations' Part VII 'Use of Radionuclides in the Healing Arts'** contains the training and experience required for authorized users in medical programs. The criteria developed by the committee should include such things as the requester's training and experience, the proposed facilities, the protocol for using radioactive material to ensure that all procedures are in accordance with good radiation safety practices, and waste disposal.

For Type A broad scope licensees or applicants for a Type A broad scope license who desire the flexibility to make certain program changes and changes to certain procedures as discussed in the '**Purpose of Guide'**, the RSC, along with executive management and the RSO, will review and approve program and procedural changes in accordance with criteria developed and approved by the RSC. The criteria for reviewing and approving such changes should include provisions for training staff before implementing new procedures and ensure that the proposed changes will not degrade the effectiveness of the currently approved program. Additionally, the audit program should include an evaluation process that will assure that changes have been properly implemented by the staff and will determine the effectiveness of changes made in achieving program goals.

NRC NUREG-1516, "*Management of Radioactive Material Safety Programs at Medical Facilities*", Chapter 2, describes the role of the radiation safety committee at medical facilities, but contains information pertinent to all broad scope programs.

For medical broad scope programs, the requirements of **12VAC5-481 'Virginia Radiation Protection Regulations' Part VII 'Use of Radionuclides in the Healing Arts'** must be met. Broad scope licensees should review other appropriate VAREGs that may apply to their licensed program, such as the VAREG ORH-720 G, 'Guidance For Medical Use of Radioactive Material', for licensees who possess radioactive material for medical use.

In addition, applicants for a Type A broad scope license who are requesting the flexibility to make some program changes and revise some procedures previously approved by VDH without amendment of the license should submit the following:

- A description of the duties and responsibilities of the RSC, including:
  -review and approval of permitted program and procedural changes prior to implementation;
  -implementation of program and procedural changes;

-audit of licensed operations to determine compliance; and
-taking appropriate actions when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence.

- A description of the process for procedure and program review and approval, including documentation of the specific change. At a minimum, documentation shall state the reason for the change and summarize the radiation safety matters that were considered prior to approval of the change.

Item 7: Radiation Safety Officer (RSO)

Rule: 12VAC5-481-450, 12VAC5-481-470, 12VAC5-481-1310, 12VAC5-481-1750, 12VAC5-481-2680

Criteria: Type A and Type B broad scope licensees must have a Radiation Safety Officer (RSO) who is qualified by training and experience in radiation protection and who is available for advice and assistance on radiological safety matters. The RSO's training and experience must include the types and quantities of licensed material to be authorized on the license. While the rule does not require Type C broad scope licensees to have an RSO, **12VAC5-481-470** requires that the licensee establish administrative controls and provisions relating to procurement of radioactive material, procedures, recordkeeping, material control and accounting, and management review to assure safe operations. Type C broad scope licensee management should appoint someone responsible for the day-to-day operation of the radiation safety program, such as an RSO.

Discussion: Each Type A and Type B program must appoint an RSO who is responsible for radiation safety and compliance with the rules for the use of radioactive material. Each Type C broad scope program should appoint an individual who is responsible for the day-to-day operation of the radiation safety program. In a Type A broad scope license the RSO is a member of the RSC and works closely with the RSC and executive management in implementing the radiation safety program. The RSO must ensure that radiation safety activities are being performed safely according to approved policies and procedures, and that all regulatory requirements are met. The RSO should have full access to all activities involving the use of radioactive material and the authority to terminate any activity, in which health and safety appear to be compromised without consulting with executive management or the RSC, if required. The applicant should submit a ‘Radiation Safety Officer Delegation of Authority’ signed by executive management. **Appendix J** contains a sample ‘Delegation of Authority’ that is acceptable to VDH.

In a Type A broad scope licensed program, the RSO typically performs a preliminary review of proposed new uses and users, prior to formally discussing the proposal with the RSC. The RSC grants the formal approval of new users and uses in a Type A broad scope license. The task of reviewing and approving proposed uses and users in a Type B broad scope licensed program is the responsibility of the RSO. In a Type C broad scope program, individuals are qualified as users if they meet the training and experience criteria described in **12VAC5-481-470**. While no licensee RSC or individual is required by the rule to make the determination that an individual is qualified to use the material possessed under the Type C broad scope license, or that a particular use of radioactive material is safe, licensee management is ultimately responsible for assuring safe operations.

The RSO performs audits of all areas of use and individuals who are authorized to use radioactive material to ensure work is done in accordance with the license, the rule, and user permit conditions. Specific duties and responsibilities of the RSO include:

- Monitoring and surveys of all areas in which radioactive material is used
- Oversight of ordering, receipt, surveys, and delivery of radioactive material
- Packaging, labeling, surveys, etc., of all shipments of radioactive material leaving the institution
- Personnel monitoring program, including determining the need for and evaluating bioassays, monitoring personnel exposure records, and developing corrective actions for those exposures approaching maximum permissible limits
- Training of all personnel
- Waste disposal program
- Inventory and leak tests of sealed sources
- Decontamination
- Investigating any incidents and responding to any emergencies
- Maintaining all required records.

The responsibilities of the RSO may not be transferred to other individuals. Many tasks and duties associated with managing the program may be assigned or delegated to other qualified individuals; however, the responsibility for these tasks and duties is with the RSO. VDH does recognize that a qualified individual will have to fill in for the RSO when the RSO will be away for short periods of time for professional conferences, vacation, or illness. However, this should not occur for extended or indefinite periods of time. Consideration should also be given to how this individual would be contacted in the event of an emergency.

When selecting an RSO, the applicant should keep in mind the duties and responsibilities of the position, select an individual who is qualified to serve as the RSO. The RSO will need a basic technical knowledge sufficient to understand, in general, the majority of the work being done with radioactive materials under his or her responsibility. VDH recognizes that an RSO cannot be an expert in all areas that might be involved in a broad scope program. The RSO should be qualified by training and experience to perform the duties required for the position. Executive management should ensure that enough time is allocated to the individual selected as the RSO to carry out the responsibilities of the position.

The applicant should review the RSO guidance provided in the VAREG corresponding to the particular type of licensed program. For example, ORH-720 F,'Guidance For Academic, Research and Development, and Other Licenses of Limited Scope', contains guidance that is appropriate for broad scope licensees who are involved in research and development.

The applicant should also be aware of specific regulatory requirements for the RSO that may apply to their licensed program. For example, **12VAC5-481 'Virginia Radiation Protection Regulations' Part VII 'Use of Radionuclides in the Healing Arts'** contains specific requirements for an RSO in a medical program. However, an individual who qualifies as a medical RSO is not necessarily qualified to be RSO in a broad scope program.

Chapters 3 and 4 of NRC NUREG 1516, "*Management of Radioactive Material Safety Programs at Medical Facilities*", describe the role of the RSO and selection of the RSO at medical facilities but also contains information pertinent to all broad scope programs.

Note:

- Applicants should provide specific information about the proposed RSO's training and experience which is relative to the licensed material requested in the application. Applicants should not submit extraneous information such as unrelated lists of publications, research grants, committee and society memberships, etc. This only serves to slow down the review process.
- It is important to notify VDH, as soon as possible, typically within 30 days, of changes in the designation of the RSO. The name and qualifications of the replacement RSO must be submitted to VDH as part of an amendment request. Applicants should review the rules for specific program areas, such as medical uses, that have specific requirements regarding changes in the RSO.

Item 8: Training For Individuals Working In Or Frequenting Restricted Areas (Occupationally exposed individuals and ancillary personnel)

Rule: 12VAC5-481-470, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-2260, 12VAC5-481-2270, 12VAC5-481-2280

Criteria: Before beginning work with or in the vicinity of licensed material, all individuals who are likely to receive an occupational dose in excess of 1 mSv (100 mrem) in a year 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.

Discussion: 12VAC5-481-2270 describes the training that licensees are required to provide individuals who, in the course of their employment, are likely to receive, in a year, an occupational dose in excess of 1 mSv (100 mrem). **12VAC5-481-2270** requires that the licensee, in determining which individuals are subject to the training requirements consider assigned activities during both normal and abnormal situations involving exposure to radiation and/or radioactive material that can reasonably be expected to occur during the life of a licensed facility. While many licensees can demonstrate that it is not likely during a normal situation for a laboratory worker, manufacturing technician, hospital technologist, or environmental services worker at their facility to receive in a year an occupational dose in excess of 1 mSv (100 mrem), these individuals and others could reasonably be expected to receive this level of exposure during abnormal situations (e.g., radioactive material left unsecured, a contamination event, or improper disposal of radioactive material in the regular trash) or, by their actions, cause others to receive this level of exposure. Untrained workers represent a potential hazard to themselves, other individuals, and property.

Licensees should not assume that safety instruction has been adequately covered by prior employment or academic training. Practical, site-specific training should be provided for all individuals prior to beginning work with or in the vicinity of licensed material. Periodic refresher training should also be provided. Topics covered should, at a minimum, include those described in **12VAC5-481-2270**. The training may take any form. Many licensees utilize videotapes or interactive on line or off line computer programs to provide training. The licensee should determine whether the training succeeded in conveying the desired information and adjust the training program as necessary. The person conducting the training should be a qualified individual who is familiar with the licensee's program.

Retraining should be performed whenever there is a change in duties or the work environment and at a frequency sufficient to ensure that all staff are adequately trained.

Applicants should review the model training program described in the appropriate VAREG corresponding to the particular type of licensed program. For example, the VAREG ORH-720 F, **‘**Guidance for Academic, Research and Development, and Other Licenses of Limited Scope’**,** describes a training program that is acceptable to VDH for licensees who are involved in research and development, and VAREG ORH-720 G, **‘**Guidance for Medical Use of Radioactive Material’ describes a training program that is acceptable to VDH for licensees who possess radioactive material for medical use.

The applicant should also be aware of additional specific training requirements that may apply to their licensed program. For example, **12VAC5-481 ‘Virginia Radiation Protection Regulations’ Part VII ‘Use of Radionuclides in the Healing Arts’** contains specific requirements for the training of individuals who will work under the supervision of medical authorized users.

Note: If you are a Type A broad scope licensee or applicant, and you want the flexibility to revise your radiation safety training program without amendment of the license as discussed in the section titled **'Purpose of this Guide'** and **Item 6** describe the process that will be used to revise and implement your submitted program.

Item 9: Radioactive Material

Unsealed and/or Sealed Radioactive Material

Rule: 12VAC5-481-400, 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-470, 12VAC5-481-500, 12VAC5-481-3740, 12VAC5-481-3760

Criteria: An application for a license will be approved if the requirements of **12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-470,** and **12VAC5-481-3760** are met.

Discussion: Applicants for a Type A broad scope license typically request any form of radioactive material with atomic numbers from 1 through 83. The applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides. When establishing individual radionuclide and total cumulative quantities, all materials possessed under the license should be included (i.e., materials received awaiting use, materials in use/process, and those categorized as waste awaiting disposal). The maximum quantity for each individual radionuclide and total cumulative possession should be commensurate with the applicant's needs, facilities, procedures, and demonstrated experience/capability.

If certain individual unsealed radionuclides will be needed in much larger quantities than described in the atomic number 1-83 request, they should be listed separately rather than increasing the possession limit for all radionuclides. Similarly, if it is known that certain radionuclides are needed only in smaller quantities, they should be listed separately.

A separate listing should also be submitted for sealed sources needed in quantities larger than that described in the atomic number 1-83 request (e.g., self-contained irradiators, instrument calibrators, sealed sources used for medical therapy, portable and non-portable gauging devices, etc.). Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that VDH can verify that they have been evaluated in a Sealed Source and Device (SSD) Registration Certificate or specifically approved on a license. Before the formalization of the SSD registration process, some older sources or devices may have been specifically approved on a license. Licensees can continue

to use those sources and devices specifically listed on their licenses. Sealed sources or devices containing sealed sources that are intended for use solely under broad scope licenses and are not transferred to another licensee need not be evaluated by VDH prior to use if: (1) the licensee is authorized to possess the requested quantity of radioactive material in unsealed form; and (2) the licensee performs its own safety evaluation in accordance with the administrative procedures required by **12VAC5-481-470** as appropriate. For example, a broad scope licensee who is authorized to possess and use any form of iridium-192 or cobalt-60 in the fabrication of sources and devices for industrial radiography may use the fabricated sources and devices to conduct its own licensed activities without first submitting the sources and devices to NRC or another Agreement State for evaluation and registration.

NRC or another Agreement State performs a safety evaluation of sealed sources and devices before authorizing a manufacturer (or distributor) to distribute them to specific licensees. The safety evaluation is documented in an SSD Registration Certificate. Copies may also be obtained by contacting the agency.

SSD Registration Certificates contain sections on "*Conditions of Normal Use*" and "*Limitation and Other Considerations of Use*". These sections may include limitations derived from conditions imposed by the manufacturer or distributor, by particular conditions of use that would reduce radiation safety of the device, or by circumstances unique to the sealed source or device. For example, working life of the device or appropriate temperature and other environmental conditions are specified. Except as specifically approved by VDH, licensees are required to use sealed sources, devices, etc., according to their respective SSD Registration Certificates. Applicants should obtain a copy of the certificate and review it with the manufacturer, distributor or with the agency, to ensure that they understand and comply with the requirements of the SSD.

If needed, an applicant for a Type A broad scope license may request authorization to possess radioactive materials with atomic numbers greater than 83 (e.g., atomic numbers 84 to 96). For this request, the applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides. Note that authorization to possess radioactive materials with atomic numbers 84 through 96 does not authorize the possession of uranium, thorium, or plutonium classified as either source material or special nuclear material. Licensees may request authorization for source material and special nuclear material when use of these materials is directly related to the use of radioactive material under the broad scope license (e.g. laboratory-scale research and development or the use of depleted uranium as shielding). Applicants should submit separate applications for the use of source and special nuclear materials for purposes not directly related to the use of radioactive material under the broad scope license (e.g., sub-critical assemblies and nuclear pacemakers).

Possession requests should be categorized into general areas of use, e.g., research and development activities, routine gauging activities, self-shielded irradiators, instrument calibrators, and medical applications.

Applicants for Type A broad scope license should review the requirements for financial assurance and decommissioning before specifying possession limits for radioisotopes with a half-life greater than 120 days. These requirements are discussed in **Item 10 'Financial Assurance and Recordkeeping for Decommissioning'** of this VAREG.

Licensees who possess radioactive materials in excess of the quantities listed in **12VAC5-481-3740** must provide with the application either of the following:

- 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 or 0.05 Sv (5 rem) to the thyroid; or
- An emergency response plan for responding to the release in accordance with the criteria listed in **12VAC5-481-440 G**.

If you are required to establish an emergency plan, guidance is provided in NRC Regulatory Guide 3.67, "*Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities*", and NRC Policy and Guidance Directive 84-14, Revision 1, "*Standard Review Plan for Emergency Plans for Fuel Cycle and Materials Licenses*". NRC NUREG 1140, "*A Regulatory Analysis on Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees, Final Report*," also contains valuable information.

Applicants for a Type B or Type C broad scope license may request any chemical or physical form of radioactive material specified in **12VAC5-481-3760**. The possession limit for a Type B broad scope license, if only one radionuclide is possessed, is the quantity specified for that radionuclide in **12VAC5-481-3760**. If two or more radionuclides are possessed, the possession limit is determined as follows. For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in **12VAC5-481-3760** for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity. The possession limit for a Type C broad scope license, if only one radionuclide is possessed, is the quantity specified for that radionuclide in **12VAC5-481-3760**. If two or more radionuclides are possessed, the sum of the ratios, determined in the same manner as discussed above, for all radionuclides possessed under the license shall not exceed unity.

Type B and Type C broad scope licensees who require materials not specified in **12VAC5-481-3760** will need to: (1) develop Type A broad scope program; or (2) carry these additional materials under a separate specific license of limited scope. The latter option would require that the licensee review the VAREG related to the specific use of this material and submit the information required by the license reviewer as described in that document. For example, applicants who require materials not specified in **12VAC5-481-3760** for purposes of research and development should review, VAREG ORH-720 F, 'Guidance For Academic, Research and Development, and Other Licenses of Limited Scope', and submit the information described therein.

Type B licensees who require quantities of material in excess of that permitted by **12VAC5-481-470** will need to: (1) develop a Type A broad scope program; or (2) carry these additional quantities under a separate specific license of limited scope, as described in the previous paragraph. Type C licensees who require quantities of material in excess of that permitted by **12VAC5-481-470** will need to: (1) develop, as appropriate, a Type A or Type B broad scope program; or (2) carry these additional materials under a separate specific license of limited scope, as described in the previous paragraph.

Applicants for broad scope license may consider limiting their possession of isotopes described in **12VAC5-481-3760** with half lives greater than 120 days below that amount permitted by **12VAC5-481-470** to avoid being required to submit certification of financial assurance or a decommissioning funding plan. See **Item 10**, 'Financial Assurance and Recordkeeping for Decommissioning' of this document for further discussion.

Possession requests should be categorized into general areas of use, e.g., non-human research and development activities, animal studies and others (specify).

Item 10: Financial Assurance and Recordkeeping for Decommissioning

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-470, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-571, 12VAC5-481-1161, 12VAC5-481-3760

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 records of information important to the decommissioning of the facility in an identified location until the site, or any area, is released for unrestricted use. Licensees must transfer these records either to the new licensee, when licensed activities are transferred or assigned, or to VDH when 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 to cover all costs associated with decommissioning. These requirements, if applicable, specify that a licensee either set aside funds for decommissioning activities or provide a guarantee that funds will be available. Applicants are required to provide financial assurance when the possession of radioactive material with a half-life 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 Certification of Financial Assurance are stated in **12VAC5-481-450 C**. A DFP contains a 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. Criteria for parent company guarantees and self-guarantees can be found in **12VAC5-481-450 C**.

NRC Regulatory Guide (RG) 3.66, "*Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72*", provides guidance acceptable to VDH staff on the information to be provided for establishing financial assurance for decommissioning and a standard format for presenting the information. A revision to RG 3.66 will incorporate new guidance related to self-guarantees. RG 3.66 also describes the information required to be submitted for a DFP. NRC NUREG-1337, Revision 1, "*Standard Review Plan for the Review of Financial Assurance Mechanisms for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72*", also provides guidance for decommissioning financial assurance reviews.

The requirements for maintaining records important to decommissioning, including the type of information required, are stated in **12VAC5-481-450 C**. All licensees are required to maintain these

records in an identified location until the site is released for unrestricted use. Careful recordkeeping of radionuclides used, including form, amount, and area used, will facilitate area release and license termination. In the event that the licensed activities are transferred to another person or entity, these records shall be transferred to the new licensee when the transfer of the licensed activities takes place. The new licensee is responsible for maintaining these records until the license is terminated. When the license is terminated, these records must be transferred to VDH.

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.

Item 11: Facilities and Equipment

Rule: 12VAC5-481-450, 12VAC5-481-470, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-630

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property.

Discussion: Applicants for all broad scope licenses need to 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 the types and quantities of radioactive materials to be used. Facilities and equipment designed to control exposure can range from a vial that contains licensed material, to buildings, fences, or exclusion areas that are between the source and the maximally exposed member of the public. These facilities not only reduce the exposure from the source but may also limit access to the source. The licensee should list and describe these facilities for the following purposes:

- To show compliance with **12VAC5-481, 'Virginia Radiation Protection Regulations'**
- To demonstrate the use of the material will be within the ALARA concept
- To meet emergency response requirements.

Licensees should consider controlling exposures through available engineering options, as well as through limiting the releases of effluents to the environment. The licensee should describe all facilities and equipment essential to achieving these goals. The licensee will also need to describe the criteria that will be used by the RSC and/or RSO, as appropriate, to review and approve of proposed facilities. Facilities and equipment used for special applications where the impact upon workers or the public could be significant if radioactive material were released accidentally need to be specifically described. These would include, for example, room irradiators, specialized iodination/tritiation facilities, alpha laboratories, radioactive waste processing facilities (including incinerators, compactors, liquid reclamation processors, etc.), radioactive waste storage facilities (including decay-in-storage locations), individual laboratories processing 3.7 gigabecquerels (GBq) (100 millicuries) or more of radioactive material per experiment or process, nuclear pharmacies, specially designed therapy rooms, and sealed source storage areas. Significant modifications affecting facilities and equipment should have prior RSO review and RSC approval before commencement of such modifications.

Also, note that if radioactive material will be used in or on animals, a description of the animal handling and housing facilities will need to be discussed. **Appendix H** of VAREG ORH-720 F, 'Guidance For Academic, Research and Development, and Other Licenses of Limited Scope', provides guidance on the information that should be addressed concerning the use of radioactive material in animals.

In your discussion of the criteria used to evaluate your facilities and equipment, you should include a discussion on how a laboratory or facility classification scheme relates to toxicity and quantity of radioactive material and your facility and equipment requirements. For example, the International Atomic Energy Agency (IAEA), as well as other health physics and industrial hygiene professional organizations, has developed classification schemes used in assessing minimum needs (e.g., equipment and facilities, user training, personnel monitoring, surveys) that consider the hazard and quantity of radioactive materials to be used (IAEA Safety Standard, Safety Series No. 1, "*Safe Handling of Radionuclides, 1973 Edition*".) Applicants may consider the development of such a classification scheme since it can be correlated with all aspects of the radiation safety program. Each applicant's scheme should be based upon the types and quantities of radioactive material anticipated to be used. The criteria used to develop the classification scheme should be provided to each RSC member for use when evaluating requests to use licensed materials.

Appendix K of this guide provides the radionuclide toxicity and laboratory classification information from IAEA, which is acceptable to the VDH staff. This table is not all-inclusive and is meant as an example only. Based on chemical/physical form, need and quantities, your classification scheme may differ from that of the IAEA excerpt. Your application will need to describe the minimum facilities and equipment requirements for each laboratory classification.

Appendix L of this guide provides additional guidance regarding facilities and equipment used to handle radioactive materials in a laboratory setting.

Provide the following on the facility diagrams:

- 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 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; and,
- If multiple locations of storage, indicate address on diagram.
- For special application facilities, you will need to specify their locations (i.e. buildings and room numbers) and special considerations that your RSC and/or RSO will use in authorizing radioactive material use. Also, describe your procedures for control, review, and approval of significant facilities or equipment modifications.

Item 12 Radiation Safety Program

Item 12.1: Audit Program

Rule: 12VAC5-481-470, 12VAC5-481-630, 12VAC5-481-990

Criteria: Applicants for Type A, Type B, and Type C broad scope licenses are required by **12VAC5-481-470** to establish administrative controls and provisions relating to management review necessary to ensure

safe operations. **12VAC5-481-630** requires the licensee to review the radiation program content and implementation, periodically (at least annually). Licensees are required by**12VAC5-481-990** to maintain records of the radiation safety program, including, (1) the provisions of the program; and (2) audits and other reviews of the program content and implementation.

Discussion:

Management and Radiation Safety Committee Audits

The application for a Type A, B, or C broad scope license should discuss executive management oversight of the licensed program and the mechanisms they will use to ensure that they are aware of **12VAC5-481, 'Virginia Radiation Protection Regulations'**, the provisions of the license, and the compliance status of the institution's license program. This oversight may include independent audits of the program, frequent meetings with the RSC and/or RSO as appropriate and periodic tours of selected facility areas.

In a Type A broad scope program, the RSC assists executive management in performing this oversight function. Detailed written procedures should be developed and implemented for the operation of the RSC to ensure that appropriate oversight is provided. The RSC should be fully aware of the operations and activities of the radiation safety office. The RSC should conduct periodic interactive management audits and evaluations of the radiation safety program's performance, including: non-conformance reports; corrective action; status reports and audits; incident investigation reports; ALARA program development and implementation; effluent releases; qualification and radiological safety training; and performance of the RSO. Results of the RSC's audit and program reviews should be reported to executive management to allow for timely and aggressive remedial actions sufficient in scope to ensure compliance with **12VAC5-481, 'Virginia Radiation Protection Regulations'** and license conditions.

Appendix M of this document contains a sample audit program that is acceptable to VDH for use in the review of most non-medical broad scope programs.

12VAC5-481-630 requires the licensee to review the radiation program content and implementation periodically (at least annually). Generally, these audits are conducted at least once every 12 months.

Internal Audits

The application should describe the audit mechanism implemented by the RSO and her or his staff, or other individual who is responsible for the day-to-day operation of the licensed program, to determine user compliance with **12VAC5-481, 'Virginia Radiation Protection Regulations'**, the terms and conditions of the VDH license, the requirements of the RSC or RSO-approved permits (as appropriate), and good health physics practices. The audit program should include routine unannounced inspections of each user's facility and practices to supplement and audit the routine monitoring performed by the user. Facility inspections should include:

- Review of user inventory and survey records
- Evaluation of user and technician training through discussion and observation of work practices
- Performance of independent surveys of user work areas
- Evaluation of compliance with **12VAC5-481, 'Virginia Radiation Protection Regulations'**, the conditions of the license, the RSC/RSO permit and safety manual requirements
- Provision for performance-based instruction to users and technical-level staff.

The types and frequencies of monitoring performed by the RSO should be indicated. The intervals of surveys and audits should be frequent enough to ensure close communications and proper surveillance of individual radioactive material users. Applicants should consider developing survey and audit schedules based on activity and use (e.g., high use facilities and users of volatile radioactive materials may be audited weekly or biweekly, intermediate use facilities may be audited monthly, and low-level facilities may be audited quarterly).

If an audit identifies violations of **12VAC5-481, 'Virginia Radiation Protection Regulations'**, the licensee should evaluate the safety significance of each violation to set priorities and identify resources to correct these violations. NRC Information Notice (IN) 96-28, "*Suggested Guidance Relating to Development and Implementation of Corrective Action*," provides guidance on this subject. Certain identified problems or potential violations may require notification or a report to the VDH. **Appendix N** of this document describes the more common VDH reporting requirements. Licensees are encouraged to contact VDH for guidance if there is any uncertainty regarding a reporting requirement. VDH routinely reviews licensees' records to verify if appropriate corrective actions were implemented in a timely manner to prevent recurrence. It is in the best interest of the licensee to identify potential violations of regulatory requirements and take necessary steps to correct them. VDH can exercise discretion and may elect not to cite the licensee for these violations if prompt and effective corrective actions are implemented.

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 to determine if, for example, operating and emergency procedures are available, are being followed, etc.

Recordkeeping

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, person(s) contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up.

Note: If you are a Type A broad scope licensee or applicant, and you want the flexibility to revise your radiation safety audit program without amendment of the license as discussed in the section titled **'Purpose of this Guide'** and **Item 6**, 'Radiation Safety Committee', describe the process that will be used to revise and implement your submitted audit program.

Item 12.2: Radiation Monitoring Instruments

Rule: 12VAC5-481-450, 12VAC5-481-470, 12VAC5-481-750, 12VAC5-481-1000, 12VAC5-481-1240, 12VAC5-481-1410, 12VAC5-481-1800, 12VAC5-481-1810, 12VAC5-481-2070, 12VAC5-481-3200

Criteria: Licensees must, pursuant to **12VAC5-481-750**, possess and periodically calibrate radiation monitoring instruments that are necessary to protect health and minimize danger to life or property.

Discussion: Licensees must possess an adequate number of radiation detection and measurement instruments as necessary and ensure they are calibrated periodically for the radiation being measured. For purposes of this document, survey instruments are defined as any device used to measure the radiological

conditions at a licensed facility. The choice of instrument needs to be appropriate for the type of radiation to be measured and for the type of measurement to be taken (count rate, dose rate, etc.).

The applicant should submit the criteria used in determining what radiation detection and monitoring equipment will be required for each type of use by authorized users and the availability of a sufficient quantity of these instruments to both the radiation safety office and authorized users (e.g., ion-chambers, GMs, air samplers, liquid scintillation counters).

VDH requires that survey instruments used to determine compliance with regulatory requirements be calibrated periodically by the instrument manufacturer or persons specifically authorized by VDH, the NRC, or another Agreement State. Survey instruments should be calibrated at least annually (every 12 months), unless otherwise specified by the rule or license condition. Licensees seeking authorization to perform their own survey instrument calibrations will need to submit calibration procedures for review. The licensee may wish to review available industry standards for calibration of instruments such as ANSI N323A-1997, "*Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments*". **Appendix O** of this document provides useful information about instrument specifications and sample calibration procedures that are acceptable to VDH.

Applicants will need to submit their method for assuring that instruments are calibrated at proper frequencies.

Note: If you are a Type A broad scope licensee or applicant, and you want the flexibility to revise your radiation monitoring instruments program without amendment of the license as discussed in the section titled **'Purpose of this Guide'** and **Item 6**, 'Radiation Safety Committee', describe the process that will be used to revise and implement your submitted program.

Item 12.3: Material Receipt and Accountability

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-470, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-750, 12VAC5-481-840, 12VAC5-481-900, 12VAC5-481-910, 12VAC5-481-1060, 12VAC5-481-1090, 12VAC5-481-3091

Criteria: Licensees must do the following:

- Develop procedures for ordering and safely opening packages of licensed material;
- Maintain records of receipt, transfer, and disposal of licensed material; 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: Applicants for a broad scope license are required to establish appropriate administrative controls and provisions that are necessary to assure safe operations including procedures to assure the control of procurement and use of radioactive material. Administrative procedures must assure that only authorized individuals receive radioactive materials and that individuals receive only the types and quantities of radioactive material that they are authorized to receive.

Applicants for a broad scope license are strongly encouraged to develop an administrative procedure to control procurement and use of radioactive material that emphasizes centralized purchasing and receipt. VDH has found centralized purchasing and receipt to be effective in controlling licensed materials

entering the licensed institution through normal commercial channels, particularly for larger institutions. Procedures must also be established to control licensed materials obtained outside of the normal channels (e.g., through the loan or transfer of materials without purchase or through surplus). **Appendix P** of this document describes a sample procedure for controlling procurement and use of radioactive material that is acceptable to VDH.

Licensees are required to develop, implement, and maintain written procedures for safely receiving and opening packages in accordance with **12VAC5-481-900** and **12VAC5-481-3091**. **Appendix P** of this document describes a sample procedure for safely receiving and opening packages containing licensed materials that is acceptable to VDH.

Applicants for a broad scope license are required to establish appropriate administrative controls and provisions relating to material control and accounting that are necessary to assure safe operations. Licensees use various methods to account for receipt, use, transfer, disposal, and radioactive decay of unsealed licensed material (e.g., computer programs, manual ledgers, log books, etc.). These methods help to assure that licensee and individual authorized user possession limits are not exceeded. Licensees who possess sealed sources are required to perform periodic inventories. The frequency of these inventories is established on the application as, at least, every 6 months.

Licensed material must be tracked from ‘cradle to grave’. ‘Cradle to Grave’ accountability refers to maintaining the radioactive material from the moment it becomes a part of your organization (receipt of, creation, etc) through performing the physical inventories (ensuring the material’s location, etc) until it leaves your organization (through transfer, return to manufacturer/distributor, or disposal to properly licensed facility).

Licensed material is considered to become part of the licensee's inventory at the time that it is received by the licensee, be it during normal working hours or after hours when delivered by the carrier in accordance with procedures established by the licensee. If, through some error, the licensee receives material it is unauthorized to possess or receives quantities of material that would result in the total inventory being in excess of license possession limits, the licensee should place the package in secure storage and arrange for the return of these materials in a timely manner. If return of the materials is not possible, the licensee should contact VDH and request issuance of an expedited license amendment. The materials must not be used until the amendment is granted.

12VAC5-481-840 requires licensees to secure radioactive materials from unauthorized removal or access while in storage and to control and maintain constant surveillance over licensed material that is not in storage. Applicants for broad scope licenses must establish policies and procedures to ensure compliance with security requirements.

Licensees must maintain records of receipt, use, transfer, and disposal of all licensed material. **Table 3** below lists each type of record and how long the record must be maintained.

Table 3: 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

Maintain inventory records that contain the following types of information:

- Radionuclide and amount (in units of Bq or curies) of radioactive material in each sealed source;
- Manufacturer's name, model number, and serial number of each sealed source;
- Manufacturer's name, model number, and serial number of each device containing depleted uranium or radioactive material;
- Location of each sealed source and device;
- Date of the inventory; and
- Name of individual performing 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).

Information about locations where licensed material is used or stored is among the records important to decommissioning and required by **12VAC5-481-450 C**. Also refer to **Item 10,** 'Financial Assurance and Recordkeeping for Decommissioning' in this document.

Note: If you are a Type A broad scope licensee or applicant, and you want the flexibility to revise your radiation safety receipt and accountability program without amendment of the license as discussed in the section titled **'Purpose of this Guide'** and **Item 6**, 'Radiation Safety Committee', describe the process that will be used to revise and implement your submitted program.

Item 12.4: Occupational Dosimetry

Rule: 12VAC5-481-640, 12VAC5-481-650, 12VAC5-481-660, 12VAC5-481-670, 12VAC5-481-700, 12VAC5-481-710, 12VAC5-481-750, 12VAC5-481-760, 12VAC5-481-830, 12VAC5-481-1040, 12VAC5-481-3760

Criteria: The use of individual monitoring devices for external dose is required, pursuant to **12VAC5-481-760**, for:

- Adults who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
  - 0.005 Sv (0.5 rem) deep-dose equivalent.
  - 0.015 Sv (1.5 rems) eye dose equivalent.
  - 0.05 Sv (5 rems) shallow-dose equivalent to the skin.
  - 0.05 Sv (5 rems) shallow-dose equivalent to any extremity.
- Minors who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
  - 1 mSv (0.1 rem) deep-dose equivalent.
  - 1.5 mSv (0.15 rem) eye dose equivalent.
  - 0.005 Sv (0.5 rem) shallow-dose equivalent to the skin.
  - 0.005 Sv (0.5 rem) shallow-dose equivalent to any extremity.

- Declared pregnant women who are likely to receive an annual dose from occupational exposures in excess of 1.0 mSv (0.1 rem) deep-dose equivalent, although the dose limit applies to the entire gestation period.
- Individuals entering a high or very high radiation area.

Internal exposure monitoring is required, pursuant to **12VAC5-481-760**, for:

- Adults likely to receive in 1 year an intake in excess of 10% of the applicable Annual Limit of Intake (ALI) for ingestion and inhalation.
- Minors and declared pregnant women likely to receive in 1 year a committed effective dose equivalent in excess of 1.0 mSv (0.1 rem).

Discussion: If an adult is likely to receive in 1 year a dose greater than 10% of any applicable limit (see **Table 4**), monitoring 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. This evaluation need not be made for every individual. Evaluations can be made for employees with similar job functions or work areas.

Table 4: 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	

If this prospective evaluation shows that the individual is not likely to exceed 10% of any applicable limit, there are no reporting requirements in regard to the individual's exposure. For individuals who received exposure at other facilities in the current year, the previous dose need not be considered in this prospective evaluation. Only dose that could be received at the facility performing the evaluation need be considered when determining the need for monitoring, and therefore, recordkeeping and reporting requirements. If it is determined that monitoring is not required and a subsequent evaluation shows that the 10% threshold has or will be exceeded, the dose received when monitoring was not provided should be estimated, recorded, and reported. These estimates can be based on any combination of work location radiation monitoring or survey results, monitoring results of individuals in similar work situations or other estimates to produce a ‘best estimate’ of the actual dose received.

If monitoring is not required to demonstrate compliance with all limits but is required relative to one or more specific limits, the licensee should enter ‘NR’ for ‘Not Required’ in the blocks on VDH Form ‘Occupational Exposure Records Per Monitoring Period’ to indicate the areas for which monitoring was not required (e.g., extremity or skin doses). Where monitoring was provided but not measurable, the licensee should enter ‘ND’ for ‘Not Detectable’.

If the prospective evaluation shows that the individual is likely to exceed 10% of an applicable limit, then monitoring and reporting of the results of monitoring performed, regardless of the actual dose received, is required. If air sampling or bioassay is required, discussion of air sampling or bioassay should provide

enough detail that the VDH staff is assured that appropriate steps will be taken to manage and monitor such exposure.

Table 5: Nuclear Regulatory Commission Documents that Contain Guidance Relating to Personnel Monitoring and Bioassay that may be Applicable

Regulatory Guide 8.7, Revision 1	Instructions for Recording and Reporting Occupational Radiation Exposure Data
Regulatory Guide 8.9, Revision 1	Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program
Regulatory Guide 8.20	Applications of Bioassay for I-125 and I-131
Regulatory Guide 8.21	Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants
Regulatory Guide 8.23	Radiation Safety Surveys at Medical Institutions
Regulatory Guide 8.25, Revision 1	Air Sampling in the Workplace
Regulatory Guide 8.34	Monitoring Criteria and Methods to Calculate Occupational Doses
Regulatory Guide 8.35	Planned Special Exposures
Regulatory Guide 8.36	Radiation Dose to the Embryo/Fetus
Regulatory Guide 8.37	ALARA Levels for Effluents from Materials Licensees
NUREG-0938	Information for Establishing Bioassay Measurements and Evaluation of Tritium Exposure
NUREG-4884	Interpretation of Bioassay Measurements
ANSI N13.30-1996	"*Performance Criteria for Radiobioassay*"

Additional References for Further Reading:

1. U.S. Department of Energy DOE G 441.1-2, "*Occupational ALARA Program Guide*".
2. U.S. Department of Energy DOE G 441.1-3, "*Internal Dosimetry Program Guide*".
3. U.S. Department of Energy DOE G 441.1-4, "*External Dosimetry Program Guide*".
4. U.S. Department of Energy DOE G 441.1-8, "*Air Monitoring Guide*".
5. U.S. Department of Energy DOE G 441.6-1, "*Evaluation and Control of Radiation Dose to the Embryo/Fetus*".

Item 12.5: Public Dose

Rule: 12VAC5-481-10, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-840, 12VAC5-481-930, 12VAC5-481-1050, 12VAC5-481-1870

Criteria: Licensees must do the following:

- Ensure that radioactive material will be used, transported, and stored 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 result in exposures to individual members of the public in excess of 0.1 mSv (10 mrem) (TEDE) in one year from those emissions;
- Control and maintain constant surveillance over licensed material that are not in storage and secure stored material from unauthorized removal or use. Licensed material should be stored away from occupied areas.

Discussion: Public dose is defined in **12VAC5-481-10** as "*the dose received by a member of the public from exposure to sources of radiation released by the licensee or registrant, or to any other source of radiation under the control of a licensee…*". Public dose excludes doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with **12VAC5-481-1870**, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with **12VAC5-481-930**. Whether the dose to an individual is an occupational dose or a public dose depends on the individual's assigned duties. It does not depend on whether the individual is in a restricted area, a controlled area, or an unrestricted area when the dose is received.

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

- Airborne radioactive material;
- Waterborne radioactive material; and
- External radiation exposure.

The licensee should review these major pathways and decide which are applicable to its operations. The licensee must ensure that the TEDE from all exposure pathways arising from licensed activities does not exceed 1.0 mSv (100 mrem) to the maximally exposed member of the public. In addition, the licensee must control air emissions, such that the individual member of the public likely to receive the highest TEDE does not exceed the constraint level of 0.1 mSv (10 mrem) per year from those emissions. If exceeded, the licensee must report this, in accordance with **12VAC5-481-1110**, and take prompt actions to ensure against recurrence.

Licensees should design a monitoring program to ensure compliance with **12VAC5-481-730**. The extent and frequency of monitoring will depend upon the nature of the licensee's operations, potential releases, exposures and pathways to cause public dose or environmental contamination. For additional guidance regarding monitoring of effluents, refer to **Item 12.7, ‘**Surveys’**.**

12VAC5-481-1050 requires that licensees maintain survey and monitoring records that demonstrate compliance with the dose limits for members of the public until VDH terminates the license.

For guidance about accepted methodologies for determining doses to members of the public, see **Appendix Q** of this document.

Item 12.6: Safe Use of Radionuclides and Emergency Procedures

Rule: 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-470, 12VAC5-481-500, 12VAC5-481-630, 12VAC5-481-720, 12VAC5-481-840, 12VAC5-481-860, 12VAC5-481-870, 12VAC5-481-880,

12VAC5-481-890, 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-2260, 12VAC5-481-3740, 12VAC5-481-3760

Criteria: Licensees are required, pursuant to the rules stated above, to:

- Keep radiation doses to workers and members of the public ALARA
- Ensure security of licensed material
- Make required notifications to VDH of events.

Discussion: Licensees are responsible for developing and implementing procedures to ensure the security and safe use of all licensed material from the time it arrives at their facility until it is used, transferred, and/or disposed. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to themselves, other workers, or members of the public.

All licensed materials that are stored in controlled or unrestricted areas must be secured from unauthorized access or removal, so that individuals who may not be knowledgeable about radioactive materials cannot be exposed to or contaminated by the material, and individuals 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 prevent persons from removing the material from the area.

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.

The applicant should develop procedures that clearly state acceptable methods to secure licensed material at your facility. Particular attention may be required at facilities that may have unusual needs due to the activities performed, such as hot cells, animal care facilities, and waste processing facilities. Applicant's security procedures may be in a separate document or included in the 'General Safety Procedures'.

Applicants should develop radioisotope-specific procedures based on the respective hazards associated with the radioisotopes. General safety guidelines are described in **Appendix R** of this document. Licensees are encouraged to use these guidelines in developing procedures for the safe use of radioisotopes.

Licensees need to identify all areas that require posting in accordance with **12VAC5-481-860**, unless they meet the exemptions listed in **12VAC5-481-870**. In addition, containers of licensed material (including radioactive waste) must be labeled in accordance with **12VAC5-481-880**, unless they meet the exemptions in **12VAC5-481-890**.

Applicants need to establish written procedures to handle emergencies ranging from a 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, individual users should have a clear understanding of their limitations in an emergency, with step-by-step instructions and clear direction of whom to contact. Emergency procedures that are acceptable to VDH are described in **Appendix R** of this document.

Emergency spill kits should be strategically placed in well-marked locations for use by all users and the radiation safety staff. All equipment should be periodically inspected for proper operation and replenished, as necessary. The licensee should also consider establishing an 'Emergency Response Team' composed of individuals experienced in various emergency response functions (e.g., radiological, medical, emergency management, security, and fire protection).

12VAC5-481-1090, 12VAC5-481-1100, and **12VAC5-481-1110** require certain incidents and emergencies be reported to VDH. **Appendix N** of this document provides examples of some events that require notification and/or reports. Note that **Appendix N** is not all inclusive, as there are other notification and/or reporting requirements that may apply to your specific program (i.e. **12VAC5-481, 'Virginia Radiation Protection Regulations', Parts V, VII, XII, etc.).**

If you plan to possess quantities of material in excess of the applicable amounts listed in **12VAC5-481-3740,** then you may also be required to submit an 'Emergency Response Plan for Responding to a Release'. See **Item 9, '**Unsealed and/or Sealed Radioactive Material', for specific information related to this requirement.

Note: If you are a Type A broad scope licensee or applicant, and you want the flexibility to revise your radiation safety safe use and emergency procedures without amendment of the license as discussed in the section titled '**Purpose of this Guide'** and **Item 6**, 'Radiation Safety Committee', describe the process that will be used to revise and implement your submitted procedures.

Item 12.7: Leak Tests

Rule: 12VAC5-481-180, 12VAC5-481-470, 12VAC5-481-740, 12VAC5-481-750, 12VAC5-481-1010, 12VAC5-481-1150, 12VAC5-481-1250, 12VAC5-481-1420, 12VAC5-481-1840, 12VAC5-481-2080, 12VAC5-481-2870, 12VAC5-481-3210

Criteria: VDH requires testing to determine whether there is any radioactive leakage from the source in the device. The agency finds testing to be acceptable if it is conducted by an organization approved by VDH**,** the NRC or another Agreement State or according to procedures approved by VDH.

Discussion: A leak test will be required for sealed/plated foil sources at six month intervals, as approved by VDH or by the NRC or another Agreement State as specified by the Sealed Source and Device (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 becquerels (Bq) (0.005 microcuries) of radioactivity.

Leak tests are not required if:

- Sources contain only hydrogen-3 (tritium)
- Sources contain only radioactive material with a half-life of less than 30 days
- Sources contain only a radioactive gas

- Sources contain 3.7 megabecquerels (MBq) (100 microcuries) or less of beta-emitting or gamma-emitting material or 370 kilobecquerels (kBq) (10 microcuries) or less of alpha-emitting material
- Sources are stored and are not being used (must be leak tested before use or transfer).

For more information regarding leak tests, see **Appendix T** of this document.

References: See Section 8.10.8 and Appendix O of NRC NUREG 1556 Vol. 18 "*Program Specific Guidance about Service Provider Licenses*", and is available electronically at NRC's web site, http://www.nrc.gov.

Item 12.8: Surveys

Rule: 12VAC5-481-470, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-630, 12VAC5-481-730, 12VAC5-481-750, 12VAC5-481-910, 12VAC5-481-1000, 12VAC5-481-1010, 12VAC5-481-1161, 12VAC5-481-1360, 12VAC5-481-1860, 12VAC5-481-2860, 12VAC5-481-3340

Criteria: Licensees are required, pursuant to the requirements listed above, to make surveys of potential radiological hazards in their workplace. Records of surveys 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 may be measurements (e.g., radiation levels measured with a survey instrument or results of wipe tests for contamination), calculation, or a combination of measurements and calculations. The licensees must interpret and evaluate such measurements and calculations to take appropriate action. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess the radiological conditions. Surveys are also used to plan work in areas where radioactive material is present and to evaluate doses to workers and individual members of the public. In certain cases, environmental monitoring may be required to demonstrate compliance with **12VAC5-481, 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation'.**

Surveys are required when it is necessary for the licensee to comply with **12VAC5-481, 'Virginia Radiation Protection Regulations',** or to evaluate a radiological hazard. Surveys that may need to be performed include:

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment.
- Measurements of radioactive material concentrations in air for areas where radioactive materials are handled or processed in unsealed form.
- Measurements of radioactive material concentrations in water that is released to the environment or to the sanitary sewer.
- Bioassays to determine the kinds, quantities, concentration, and 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.
- 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, such as those listed above.

12VAC5-481, 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation' 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.

Appendix S of this document describes survey procedures that are acceptable to VDH.

NRC NUREG/BR-0241, "*NMSS Handbook for Decommissioning Fuel Cycle and Materials Licenses*", contains the current regulatory guidance concerning decommissioning of facilities and termination of licenses. Appendix B of the handbook contains a comprehensive list of NRC's decommissioning regulations and guidance. In addition, NUREG-1575, "*Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)*", should be reviewed by licensees who have large facilities to decommission.

Note: If you are a Type A broad scope licensee or applicant, and you want the flexibility to revise your radiation safety survey program without amendment of the license as discussed in the section titled **'Purpose of this Guide'** and **Item 6**, 'Radiation Safety Committee', describe the process that will be used to revise and implement your submitted program.

Item 12.9: Termination of Activities

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-571, 12VAC5-481-1161, 12VAC5-481-3750

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: A licensee shall notify VDH if residual radioactivity is present and if levels make the building or outdoor area unsuitable for release according to VDH requirements. A licensee's determination that a facility is not contaminated is subject to verification by VDH inspection.

The permanent cessation of principal activities in an individual room or laboratory may require the licensee to notify VDH if no other licensed activities are being performed in the building. This also applies to buildings that were approved by the broad scope licensee as locations of use but not specifically named on the broad scope license.

NRC Draft Regulatory Guide DG-4006, "*Demonstrating Radiological Criteria For License Termination*", and NUREG/BR-0241, "*NMSS Handbook for Decommissioning Fuel Cycle and Materials Licenses*", contains the current regulatory guidance concerning decommissioning of facilities and termination of licenses. Appendix B of the Handbook contains a comprehensive list of NRC's decommissioning regulations and guidance. NUREG-1575, "*Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)*", should be reviewed by licensees who have large facilities to decommission. An acceptable screening computer code for calculating screening values to demonstrate compliance with the unrestricted dose limits is D and D, Version 1; this was issued on August 20, 1998. Supplemental information on the implementation of the final rule on radiological criteria for license termination was published in the Federal Register (Volume 63, Number 222, Page 64132-64134) on November 18, 1998. This includes the following acceptable license termination screening values of common radionuclides for building surface contamination.

Table 6: Acceptable License Termination Screening Values of Common Radionuclides for Building Surface Contamination

Radionuclide	Symbol	Acceptable Screening Levels*
hydrogen-3 (tritium)	^{3}H	1.2×10^{8}
carbon-14	^{14}C	3.7×10^{6}
sodium-22	^{22}Na	9.5×10^{3}
sulfur –35	^{35}S	1.3×10^{7}
chlorine-36	^{36}Cl	5.0×10^{5}
Manganese-54	^{54}Mn	3.2×10^{4}
iron-55	^{55}Fe	4.5×10^{6}
cobalt-60	^{60}Co	7.1×10^{3}
nickel-63	^{63}Ni	1.8×10^{6}
Strontium-90	^{90}Sr	8.7×10^{6}
Technetium-99	^{99}Tc	1.3×10^{6}
iodine-129	^{129}I	3.5×10^{4}
cesium-137	^{137}Cs	2.8×10^{4}
iridium-192	^{192}Ir	7.4×10^{4}

* 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, based on site-specific re-suspension factor. For Unrestricted Release (dpm/100 cm^2) 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 may 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 **12VAC5-481-3750**.

Item 12.10: Transportation

Rule: 12VAC5-481-100, 12VAC5-481-470, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-880, 12VAC5-481-900, 12VAC5-481-1290, 12VAC5-481-1880, 12VAC5-481-2980, 12VAC5-481-3000, 12VAC5-481-3010, 12VAC5-481-3020, 12VAC5-481-3030, 12VAC5-481-3040, 12VAC5-481-3051, 12VAC5-481-3070, 12VAC5-481-3080, 12VAC5-481-3091, 12VAC5-481-3710, 49 CFR Parts 171-178

Criteria: Applicants must develop, implement, and maintain safety programs for public transport of radioactive material to ensure compliance with DOT regulations.

Discussion: DOT regulations (**49 CFR**) were written to help assure that transportation of hazardous materials in commerce is transported uniformly and safely. VDH licensees who transport radioactive material (hazardous material) in commerce would, therefore, be required to comply with all applicable regulations found in DOT. However, many VDH licensees routinely transport radioactive material that is not in commerce. **Appendix U** of this document provides an overview of the transportation requirements commonly affecting VDH licensees. Licensees may also wish to review NUREG-1660, "*U.S.-Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments*".

Knowing how **12VAC5-481-2980** and **49 CFR** interrelate is very important to broad scope programs. Therefore, it is imperative that your radiation safety staff is thoroughly familiar with **12VAC5-481-2980** and **49 CFR** in order to comply and to take full advantage of the flexibility inherent in DOT requirements.

Licensed material, including radioactive waste, must be packaged and transported in accordance with VDH and DOT requirements, if the transportation involves the use of public highways. In addition, broad scope licensees need to develop and maintain their own radiation safety procedures for transporting licensed material within their own facilities if such transportation does not involve the use of public highways.

Licensees also need to consider the safety of all individuals who may handle or may come in contact with the packages containing licensed material. Thus, the primary considerations in packaging licensed material should be to ensure that package integrity is not compromised during transport and that the radiation levels (including removable contamination levels) at the package surfaces not only meet the regulatory requirements of **12VAC5-481-2980**, but are ALARA.

Licensees shipping radioactive waste for disposal must prepare appropriate documentation as specified in **12VAC5-481-3710**.

Reference: ‘A Review of Department of Transportation Regulations for Transportation of Radioactive Materials (1998 revision)’ can be obtained by calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4900 or by accessing their website at http://hazmat.dot.gov/pubtrain/ramreview.pdf.

Item 13: Waste Management

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-730, 12VAC5-481-840, 12VAC5-481-910, 12VAC5-481-920, 12VAC5-481-930, 12VAC5-481-940, 12VAC5-481-950, 12VAC5-481-960, 12VAC5-481-970, 12VAC5-481-971, 12VAC5-481-1060, 12VAC5-481-1890, 12VAC5-481-2571, 12VAC5-481-2572, 12VAC5-481-2980, 12VAC5-481-3690

Criteria: Licensed materials must be disposed of in accordance with VDH requirements by transfer to an authorized recipient. Appropriate records must be maintained.

Discussion: The applicant should discuss the methods for 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. Licensees may not receive radioactive waste from other licensees for processing, storage, or disposal unless specifically authorized.

The U.S. Environmental Protection Agency (EPA) issued guidance for developing a comprehensive program to reduce hazardous waste. This guidance was transmitted to NRC licensees by the NRC in IN-94-23, "*Guidance to Hazardous, Radioactive, and Mixed Waste Minimization Program*". The application should include, where appropriate for the types of waste involved, provisions for monitoring and segregating waste materials (radioactive from non-radioactive, short from long half-life, liquid from solid waste, etc.).

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

Transfer to an Authorized Recipient

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 VDH and DOT 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.

Decay-In-Storage (DIS) and Extended Interim Storage

VDH has concluded that materials with half-lives of less then or equal to 120 days are appropriate for DIS and interim storage. The minimum holding period for decay is ten half-lives of the longest lived radioisotope in the waste. 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.
Used syringes/needles and vials are considered both biohazardous and radioactive waste since these items may be contaminated with the patients' blood or other body fluids. Following completion of decay-in-storage, such waste may be disposed of as biohazardous waste (medical waste) 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.

Radioactive material labels on the used syringes/needles cannot be defaced without exposing employees to the risk of injury from the needles. Additionally, exposing employees to the risk of injury from needles would place licensees in violation of the Occupational Safety and Health Administration (OSHA) regulations in **29 CFR 1910.1030(d)(1)**, which requires precautions to prevent contact with blood or other potentially infectious materials, including recommendations not to manipulate used syringes/needles by hand. Thus, radiopharmacy licensee's do not have to deface or remove radiation labels from individual containers and packages (e.g., syringes, vials) inside waste barrels/containers intended for disposal as medical waste, provided the following conditions are met:

- The radioactive material labels on the outer waste barrels/containers will be defaced or removed prior to transfer to waste disposal firm; Waste barrels are sealed prior to delivery to the waste disposal firm;
- Waste barrels/containers will be delivered directly from the licensee's facility to a waste disposal firm for disposal;
- Medical waste is incinerated, and not sent to a medical waste landfill; and
- The waste disposal firm is notified that the barrels must not be opened at any point, and for any reason, prior to incineration.

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. NRC Information Notice No. 90-09, "*Extended Interim Storage of Low-Level Radioactive Waste for Fuel Cycle and Material Licensees*", provides guidance to licensees for requesting an amendment to authorize extended interim storage of LLW.

A sample procedure for DIS is contained in **Appendix V** of this guidance document.

Release into Air and Water

Release of radioactive material into air and water must conform to the requirements described in **12VAC5-481-730**. 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. Applicants, who are considering release of radioactive material into air and water, should review NRC Regulatory Guide 8.37, "*ALARA Levels for Effluents From Materials Facilities*". Regulatory Guide 8.37 deals with the application of ALARA in controlling gaseous and liquid effluents, and references documents containing acceptable methods of effluent monitoring.

Licensees considering disposal by release to the sanitary sewerage system must comply with the requirements of **12VAC5-481-930**. **12VAC5-481-930** authorizes disposal of licensed material by release into a public sanitary sewerage system if certain conditions are met. Licensees are responsible for

demonstrating that licensed materials discharged into the public sewerage system are readily soluble in water or are biological materials that are readily dispersible in water. NRC Information Notice, No. 94-07, "*Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20*", provides the criteria for evaluating solubility of waste. Licensees should carefully consider the possibility of re-concentration of radioisotopes that are released into the sewer. The NRC alerted licensees to the potentially significant problem of re-concentration of radionuclides released to sanitary sewerage systems in NRC's Information Notice No. 84-94, "*Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems Permitted Under 10 CFR 20.203* (now 10 CFR 20.2003)".

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 rule. Licensees are required to maintain accurate records of all releases of licensed material into the sanitary sewerage. A sample procedure for disposal of radioactive waste via sanitary sewer and maintenance of records is described in **Appendix V** of this guidance document.

If your facility maintains a private sewerage treatment system, a septic system, or leach fields, the requirements of **12VAC5-481-930** are not applicable for releases to these systems (see **12VAC5-481-10**, definition of "S*anitary Sewerage*"). 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. 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 VDH, 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**. Applicants proposing incineration should be aware that notification and approval by the Virginia Department Environmental Quality (VDEQ) is required before ash may be disposed of as ordinary waste in the Commonwealth of Virginia. However, approval of incineration pursuant to **12VAC5-481-940** does not require notification and approval by the VDEQ if the ash is disposed as radioactive waste or transferred to a specific licensee. Nuclear Regulatory Commission (NRC) Policy and Guidance Directive PG 8-10, "*Disposal of Incinerator Ash as Ordinary Waste*", provides guidance relative to the disposal of ash. A sample procedure for incineration of waste is described in **Appendix V** of this guidance document.

Applicants who are considering disposal of radioactive material by incineration should review NRC Regulatory Guide 8.37, "*ALARA Levels for Effluents From Materials Facilities*". Regulatory Guide 8.37 deals with 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 detail, in the application. A sample procedure for waste compaction is described in **Appendix V** of this guidance document.

Disposal of Specific Waste as If It Were Not Radioactive

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

- Liquid scintillation medium containing no more than 1.85 kBq (0.05 microcuries) of hydrogen-3, iodine-125, or carbon-14 per gram of the medium; and/or
- Animal carcasses or animal tissue containing no more than 1.85 kBq (0.05 microcuries) of hydrogen-3, iodine-125, or carbon-14 per gram averaged over the weight of the entire animal.

Applicants should have procedures that will ensure that 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. Licensees must maintain accurate records of these disposals.

Burial

Licensees who were previously authorized by the NRC to bury radioactive materials pursuant to **10 CFR 20.304** prior to January 28, 1981, should describe the locations, condition and current status of these former sites (i.e., controlled or uncontrolled), active monitoring of the site, and current condition of burial site.

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

Applicants may also request alternate methods for the disposal of radioactive waste generated at their facilities. Such requests 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.

The application should: (1) describe the ALARA considerations taken before disposal of radioactive materials; and (2) discuss the potential for unmonitored or unanticipated release of radioactive materials to 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 **12VAC5-481-3690.** Furthermore, due to the variability of inventory control programs for monitoring disposal and releases of radioactive material in use, a program for physically measuring releases should be in place whenever releases exceed the specified ALARA action point.

Applicants should contact VDH for guidance on how to obtain approval for alternate methods.

Sealed Sources

Because of the difficulties and costs associated with disposal of sealed sources, applicants should preplan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement.

Security Program

Rule: 12VAC5-481-451, 12VAC5-481-840, 12VAC5-481-1151

Criteria: Licensees must ensure the security and control of licensed material.

Discussion: **12VAC5-481-840** requires licensees to secure radioactive materials from unauthorized removal or access while in storage and to control and maintain constant surveillance over licensed material that is not in storage.

12VAC5-481-1151 requires that each licensee who manufacturers, transfers, receives, disassembles, or disposes of a nationally tracked source complete and submit a National Source Tracking Transaction Report. The NSTS is a secure, accessible, and easy-to-use computer system that tracks high –risk radioactive sources from the time they are manufactured or imported through the time of their disposal or export, or until they decay enough to no longer be of concern.

12VAC5-481-451 requires licensees to implement enhanced security to control access to Category 1 and Category 2 quantities radioactive materials and to protect sensitive security related information. The same regulation also requires fingerprinting and criminal history checks for all individuals with unescorted access to Category 1 and Category 2 quantities radioactive materials. The specific radionuclides and associated thresholds were based on the Category 1 and Category 2 quantities described in International Atomic Energy Agency's "*Code of Conduct on the Safety and Security of Radioactive Sources*."

Refer Appendix Q for additional guidance for implementing security plan for physical protection of category 1 and category 2 quantities of radioactive material.

Item 14: License Fees

For a listing of application fees, please see **12VAC5-490**. On VDH Form, 'Application for Radioactive Material for Broad Scope', enter the appropriate fee category and the amount.

Item 15: Certification

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

Note:

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

    - **Note:** Applicants do not need to provide information to VDH if they plan to dispose of Low Level Waste via transfer to an authorized recipient or to dispose of liquid scintillation media or animals containing low levels of hydrogen-3, iodine-125 or carbon-14, as authorized by **12VAC5-481-950**.

Appendix A:

VDH Form,
‘Application for Radioactive Material License for Broad Scope’

THE FORM IS LOCATED AT:

HTTP://WWW.VDH.STATE.VA.US/EPIDEMIOLOGY/RADIOLOGICALHEALTH/MATERIALS/FORMS.HTM

Attachment A
Broad Scope 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 5	Attached description of administrative controls and an organization chart
		Item 6	Attached description of the Radiation Safety Committee duties and responsibilities and criteria for selecting members and approving users and uses
		Item 7	Checked box(es) and attached training information
		Item 8	Checked box and attached training course information
		Item 10	Checked box and attached financial assurance information, if needed
		Item 11	Checked box and attached facility diagram(s)
		Item 12.1	Checked box(es) and attached description of management oversight and audit program
		Item 12.2	Checked box(es) and attached description of monitoring instruments, including calibration
		Item 12.3	Checked box(es) and attached procurement procedure, including security and opening packages
		Item 12.6	Checked box(es) and attached safe use procedure, as needed
		Item 12.7	Checked box(es) and attached alternate procedure, as needed
		Item 12.8	Checked box(es) and attached survey procedure, as needed
		Item 13	Checked box and attached waste procedure

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 **12VAC5-481-510**. 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 **12 VAC 5-481-510.** (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:

RESERVED

Appendix D:

RESERVED

Appendix E:

RESERVED

Appendix F:

RESERVED

Appendix G:

RESERVED

Appendix H:

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 an 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; some licensees refer to this as 'transferring 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 VDH 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

Appendix I:

Information Needed for Field Use of Radioactive Material

Information Needed for Field Use of Radioactive Material

If you desire to perform field studies in which licensed material is deliberately released to the environment for the purposes of studies, please provide the following information:

1. A complete application describing the type and amount of material to be used, the location of use, and training and experience of the individual using the material.
2. A complete experimental protocol.
3. A description of the amount of radioactive material to be released in the field, decontamination procedures at the conclusion of the experiment, if appropriate, and procedures for minimizing releases.
4. A description of the expected radiation dose to humans.
5. A description of the proposed methods of disposal of radioactive waste generated during the field use of radioactive material.
6. Written permission from the property owner to use radioactive materials at the proposed site.

Appendix J:

Sample Delegation of Authority for the Radiation Safety Officer

Memorandum To: All Employees

From: Chief Executive Officer

Subject: Delegation of Authority for Radiation Safety Officer

_____ has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radioactive material. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with rules for the use of radioactive material. The Radiation Safety Officer is hereby delegated the authority necessary to meet these responsibilities.

The Radiation Safety Officer has the authority to immediately stop any operations involving the use of radioactive material in which health and safety may be compromised or may result in non-compliance with VDH requirements.

_____ _____

Signature Date

_____

Title

Appendix K:

Radionuclides Classified According to Relative Toxicity

(Excerpted from IAEA Safety Standard, Safety Series No. 1, "*Safe Handling of Radionuclides, 1973 Edition*")

This table is not all-inclusive and is meant to be used as an example only. Based on chemical/physical form, need and quantities, your classification scheme may differ from that of the IAEA excerpt.

Table 7: Radionuclides Classified According to Relative Radiotoxicity (Excerpted from IAEA Safety Standard, Safety Series No. 1, "*Safe Handling of Radionuclides, 1973 Edition*")

Group 1: Very High Radiotoxicity									
^{210}Pb	^{226}Ra	^{227}Th	^{231}Pa	^{233}U	^{238}Pu	^{243}Am	^{244}Cm	^{249}Cf	
^{210}Po	^{228}Ra	....	....	....	....	....	....	....	
Group 2: High Radiotoxicity									
^{22}Na	^{56}Co	^{95}Zr	^{125}Sb	^{131}I	^{144}Ce	^{181}Hf	^{207}Bi	^{228}Ac	
^{36}Cl	^{60}Co	^{125}I	^{192}Ir	....	....	....	....	....	
Group 3: Moderate Radiotoxicity									
^{7}Be	^{48}Sc	^{65}Zn	^{91}Sr	^{103}Ru	^{125m}Te	^{140}La	^{153}Gd	^{187}W	^{198}Au
^{14}C	^{48}V	^{69m}Zn	^{90}Y	^{32}P	^{35}S	^{51}Cr	^{24}Na	....	....
Group 4: Low Radiotoxicity									
^{3}H	^{58m}Co	^{71}Ge	^{87}Rb	^{97}Nb	^{103m}Rh	^{131m}Xe	^{125}Cs	^{191m}Os	^{232}Th
^{15}O	^{85}Kr	^{99m}Tc	....	....	....	....	....	....	....

Table 8: Limitations on Activities in Various Types of Working Place or Laboratory

Radiotoxicity of Radionuclides	Minimum Quantity	Type of Working Place or Laboratory Required		
	µ Ci	Type C	Type B	Type A
1. VERY HIGH	0.1 (3.7 kBq)	<10 µ Ci (<370 kBq)	10 µ Ci (370 kBq)	10 µ Ci or more (>370 kBq)
2. HIGH	1.0 (37 kBq)	<100 µ Ci (<3.7 MBq)	100 µ Ci (3.7 MBq)	100 µ Ci or more (>3.7 MBq)
3. MODERATE	10 (370 kBq)	<1 mCi (<37 MBq)	1 mCi - 1 Ci (37 MBq - 37 GBq)	1 Ci or more (>37 GBq)
4. LOW	100 (3.7 MBq)	<10 mCi (<370 MBq)	10 mCi - 10 Ci (370 MBq - 370 GBq)	10 Ci or more (>370 GBq)

Appendix L:

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 licensee will use or otherwise have available. Not every 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 (see the list detailed under **Item 11**) should be submitted showing the relationship between restricted areas and unrestricted areas and the location of all pertinent safety-related equipment.

- 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, sealable 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.

- 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 and isolated to contain radioactivity.

- Designated areas should be provided, for coats and personal belongings, to avoid contamination.

- Areas with the lowest possible background radiation levels should be designated for personnel dosimetry storage when not in use.

- Areas of use should be well lit 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 **12VAC5-481-810, 12VAC5-481-820,** and **12VAC5-481-830**.

Appendix M:

Audit Program - Non-Medical

The following audit form may be used by licensees to self-assess the adequacy of the licensed program, identify program weaknesses, and allow licensees to take early corrective actions (before a VDH inspection). This form is not intended to be all-inclusive. During an audit, the auditor needs to keep in mind not only the requirements of **12VAC5-481, 'Virginia Radiation Protection Regulations'**, but also the licensee's commitments in its applications and other correspondence with VDH. Licensees are encouraged to modify the audit form as needed to include items specific to their licensed program. The auditor should also evaluate whether the licensee is maintaining exposures to workers and the general public as low as is reasonably achievable (ALARA) and, if not, make suggestions for improvement. References are included at the end of this audit form.

1. **MANAGEMENT OVERSIGHT**:
   Management support to radiation safety; RSC; RSO; program audits, including annual reviews of program and ALARA reviews; control by authorized users; appropriate follow up on events and previous audit/inspection findings

2. **AMENDMENTS AND PROGRAM CHANGES:**
   Amendments to the license were properly implemented; if applicable, program and procedural changes were approved and implemented in accordance with license condition

3. **FACILITIES:**
   Facilities as described in license; uses; control of access; engineering controls; calibration facilities; shielding; airflow

4. **EQUIPMENT AND INSTRUMENTATION:**
   Operable and calibrated survey equipment; procedures

5. **MATERIAL USE, CONTROL, AND TRANSFER:**
   Materials and uses authorized; security and control of licensed materials; and procedures for receipt and transfer of licensed material

6. **AREA RADIATION SURVEYS AND CONTAMINATION CONTROL:**
   Radiological surveys; air sampling; leak tests; inventories; handling of radioactive materials; contamination controls; records; and public doses

7. **TRAINING AND INSTRUCTIONS TO WORKERS:**
   Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities; **12VAC5-481, 'Virginia Radiation Protection Regulations', Parts IV and X** requirements; emergency situations; and supervision by authorized users

8. **RADIATION PROTECTION:**
Radiation safety program with ALARA provisions; external and internal dosimetry; exposure evaluations; dose and survey records and reports; annual notifications to workers; information notices and other generic communications

9. **RADIOACTIVE WASTE MANAGEMENT:**
Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment; incinerators, hoods, vents, and compactors; license conditions for special disposal method

10. **DECOMMISSIONING:**
Records relevant to decommissioning; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements; changes in radiological conditions since decommissioning plan was submitted

11. **TRANSPORTATION:**
Quantities and types of licensed material shipped; packaging design requirements; shipping papers; hazardous materials (HAZMAT) communication procedures; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; records; and reports

12. **NOTIFICATIONS AND REPORTS:**
Reporting and follow-up of theft, loss, incidents and overexposures; notifications of changes in RSO and/or authorized user; radiation exposure reports provided to individuals.

13. **POSTING AND LABELING:**
License documents; **12VAC5-481, 'Virginia Radiation Protection Regulations', Parts IV and X**; operating procedures – location of previous three documents may be posted on a notice; Notice to Employees; emergency procedures; notices of violations; posting of radiation areas; and labeling of containers of licensed material

14. **INDEPENDENT AND CONFIRMATORY MEASUREMENTS:**
Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with staff's results and rule

15. **AUDIT FINDINGS:**

REFERENCES

A. MANAGEMENT OVERSIGHT

1. Radiation Safety Committee

   Applicable license conditions.

2. Radiation Safety Officer

   Applicable license conditions.

3. Audits, Reviews, or Inspections

   12VAC5-481-630 Radiation safety programs.

   12VAC5-481-990 Records of radiation safety programs.

   Applicable license conditions.

4. ALARA

   12VAC5-481-630 Radiation safety programs.

5. Authorized Users

   Applicable license conditions.

B. AMENDMENTS AND PROGRAM CHANGES:

   Applicable license conditions.

C. FACILITIES

1. Access Control

   12VAC5-481-780 Control of access to high / very high radiation areas.
   12VAC5-481-790
   12VAC5-481-840 Security of stored material.

   12VAC5-481-840 Control of material not in storage.

   Applicable license conditions.

2. Engineering Controls

   12VAC5-481-630 Radiation safety programs.

   12VAC5-481-810 Use of process or other engineering controls.

   Applicable license conditions.

D EQUIPMENT AND INSTRUMENTATION

1. Survey Instruments

12VAC5-481-750	General.
12VAC5-481-810	Use of Process or Other Engineering Controls.
12VAC5-481-1000	Records of Surveys.

Applicable license conditions.

E. MATERIAL USE, CONTROL, AND TRANSFER

1. License and Applicable License Conditions.

2. Security and Control

12VAC5-481-10	Definitions (restricted area and unrestricted area).
12VAC5-481-840	Security of stored material.
12VAC5-481-840	Control of material not in storage.

3. Receipt and Transfer of Licensed Material

12VAC5-481-730	Compliance with dose limits for individual members of the public.
12VAC5-481-900;	Procedures for receiving and opening packages.
12VAC5-481-3091	Opening instructions.
12VAC5-481-750	Surveys.
12VAC5-481-1000	Records of surveys.
12VAC5-481-570	Transfer of radioactive material.
12VAC5-481-100	Records.
12VAC5-481-571	Receipt, transfer, and disposal records.
12VAC5-481-3100	Shipment records.

F. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

1. Area Surveys

12VAC5-481-730	Compliance with dose limits for individual members of the public.
12VAC5-481-750	General.
12VAC5-481-1000	Records of surveys.
12VAC5-481-1050	Records of dose to individual members of the public.

Applicable license conditions.

2. Leak Tests and Inventories

12VAC5-481-740 Testing for leakage or contamination of sealed sources.

Applicable license conditions.

G. TRAINING AND INSTRUCTIONS TO WORKERS

1 General

a. **12VAC5-481-2270** Instruction to workers

b. Knowledge of **12VAC5-481 Part IV** Radiation protection procedures and requirements.

c. Application license conditions

H. RADIATION PROTECTION

1. Radiation safety program

a. Exposure evaluation

b. Programs

12VAC5-481-630 Radiation safety programs.

2 Dosimetry

a. Dose Limits

12VAC5-481-650 Compliance with requirements for summation of external and internal doses.

12VAC5-481-700 Occupational dose limits for minors.

12VAC5-481-710 Doses to an embryo/fetus.

b. External

12VAC5-481-660 Determination of external dose from airborne radioactive material.

12VAC5-481-750 General.

12VAC5-481-760 Conditions requiring individual monitoring of external and internal occupational dose.

Applicable license conditions.

c. Internal

12VAC5-481-670 Determination of internal exposure.

12VAC5-481-760 Conditions requiring individual monitoring of external and internal occupational dose.

12VAC5-481-810 Use of process or other engineering controls.
12VAC5-481-820 Use of other controls.
12VAC5-481-830 Use of individual respiratory protection equipment.

3. Records

12VAC5-481-990 Records of radiation safety programs.

12VAC5-481-1000 Records of surveys.

12VAC5-481-680 Determination of prior occupational dose.
12VAC5-481-1020 Records of prior occupational dose.

12VAC5-481-1040 Records of individual monitoring results.

I. RADIOACTIVE WASTE MANAGEMENT

1. Disposal

12VAC5-481-880 Labeling containers and radiation machines.

12VAC5-481-910 General requirements.

12VAC5-481-1000 Records of surveys.

12VAC5-481-1060 Records of waste disposal.

12VAC5-481-930 Disposal by release into sanitary sewerage.

2 Effluents

a. General

Applicable license conditions

b. Release to septic tanks

12VAC5-481-10 Definitions (sanitary sewerage).

12VAC5-481-3690

c. Incineration of waste

12VAC5-481-940 Treatment or disposal by incineration.

d. Control of air effluents and ashes

12VAC5-481-640 Occupational dose limits for adults.

12VAC5-481-720 Dose limits for individual members of the public.

12VAC5-481-750 General.

12VAC5-481-810 Use of process or other engineering controls.

Applicable license conditions

3. Waste Management

a. General

12VAC5-481-910 General requirements.

NRC Information Notice (IN) 90-09 "*Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees*".

b. Waste compacted

Applicable license conditions.

c. Waste storage areas

12VAC5-481-840 Security of stored material.

12VAC5-481-860 Posting requirements.

12VAC5-481-880 Labeling containers and radiation machines.

Applicable license conditions.

d. Packaging, Control, and Tracking

12VAC5-481-960 Transfer for disposal and manifests.

e. Transfer

12VAC5-481-910 General requirements.

12VAC5-481-960 Transfer for disposal and manifests.

f. Records

12VAC5-481-1000 Records of surveys.

12VAC5-481-1060 Records of waste disposal.

J. DECOMMISSIONING

12VAC5-481-450 C Financial assurance and recordkeeping for Decommissioning.

12VAC5-481-510 Expiration and termination of licenses and decommissioning of sites and separate building or outdoor areas.

12VAC5-481-1161 Radiological criteria for license termination.

K. TRANSPORTATION

1. General

12VAC5-481-2980 Transportation of licensed material.

2. Shippers - Requirements for Shipments and Packaging

a. General Requirements

49 CFR Part 173, Subpart I Class 7 (radioactive) materials

49 CFR 173.24	General requirements for packaging and packages.
49 CFR 173.448	General transportation requirements
49 CFR 173.435	Table of A1 and A2 values for radionuclides

b. Transport Quantities

12VAC5-481-10	Definitions.

i. All quantities

12VAC5-481-10	Definitions.
49 CFR 173.410	General design requirements.
49 CFR 173.431	Activity limits Type A and Type B
49 CFR 173.441	Radiation level limitations.
49 CFR 173.443	Contamination control.
49 CFR 173.475	Quality control requirements prior to each shipment of Class 7 (radioactive) materials.
49 CFR 173.476	Approval of special form Class 7 (radioactive) materials.

ii. Limited quantities

49 CFR 173.421	Excepted packages for limited quantities of Class 7 (radioactive) materials.
49 CFR 173.422	Additional requirements for excepted packages containing Class 7 (radioactive) materials.

iii. Type A quantities

49 CFR 173.412	Additional design requirements for Type A packages.
49 CFR 173.415	Authorized Type A packages.
49 CFR 178.350 Specification 7A;	General packaging, Type A.

iv. Type B quantities

49 CFR 173.416	Authorized Type B packages
49 CFR 173.467	Package testing

v. LSA material and SCO

49 CFR 173.403	Definitions.
49 CFR 173.427	Transport requirements for low specific activity (LSA) Class 7 (radioactive) materials and surface contaminated objects (SCO).

c HAZMAT Communication Requirements

49 CFR 172.200-205	Shipping papers.

49 CFR 172.300-338	Marking.
49 CFR 172.400-450	Labeling.
49 CFR 172.500-560	Placarding.
49 CFR 172.600-604	Emergency response information.

3. HAZMAT Training

49 CFR 172.702	Applicability and responsibility for training and testing.
49 CFR 172.704	Training requirements.

4. Transportation by Public Highway

49 CFR 171.15	Immediate notice of certain hazardous materials incidents.
49 CFR 171.16	Detailed hazardous materials incident reports.
49 CFR 177.800	Purpose and scope of this part and responsibility for compliance and training.
49 CFR 177.816	Driver training.
49 CFR 177.842	Class 7 (radioactive) material.

L. NOTIFICATIONS AND REPORTS

12VAC5-481-2280	Notifications and reports to individuals.
12VAC5-481-1090	Reports of stolen, lost, or missing licensed or registered sources of radiation.
12VAC5-481-1100	Notification of incidents.
12VAC5-481-1110	Reporting requirements.
12VAC5-481-330	Report of changes.

M. POSTING AND LABELING

12VAC5-481-2260	Posting of notices to workers.
12VAC5-481-860	Posting requirements.
12VAC5-481-870	Exemptions to posting requirements.
12VAC5-481-880	Labeling containers and radiation machines.
12VAC5-481-890	Exemptions to labeling requirements.

Appendix N:

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 mrems)	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 O:

Instrument Specifications and Model Survey Instrument and Air Sampler Calibration Programs

Radiation Monitoring Instrument Specifications

The specifications in **Table 10** will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facility(ies).

Table 10. Typical Survey Instruments (instruments used to measure radiological conditions at licensed facilities).

Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	**Radiation**	**Energy Range**	**Efficiency**
Exposure Rate Meters	Gamma, X-ray	µR-R	N/A
Count Rate Meters			
GM	Alpha	All energies (dependent on window thickness)	Moderate
	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	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
- Biological effects of radiation

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

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

Facilities and Equipment
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
- Approximate the same energy and type of radiation as the environment in which the calibrated device will be employed
- 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 cesium-137 or 7.8×10^{2} megabecquerels (21 mCi) of cobalt-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 x 10^{-4} coulomb/kilogram/hour (1 R/hr) need not be calibrated, but such scales should be checked for operation and response to radiation.
- 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
- 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

- The name of the person who performed the calibration and the date it was performed.

The following information will 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
- 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 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.

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:

$$V_s = V_1 * (P_1/760) * (273/T_1)$$

where V_s = volume at standard pressure and temperature (760 mm Hg and 273K)
V_1 = volume measured at conditions P_1 and T_1
T_1 = temperature of V_1 in K
P_1 = pressure of V_1 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:

1. NRC NUREG 1556 Vol. 18, "*Program-Specific Guidance about Service Provider Licenses*".
2. NRC Regulatory Guide 8.25, Revision 1, "*Air Sampling in the Workplace*".
3. NRC NUREG-1400, "*Air Sampling in the Workplace*".
4. The Health Physics & Radiological Health Handbook, 3rd Ed. Edited by Bernard Shleien, Lester A. Slaback, Jr., and Brian Kent Birky.
5. ANSI N323A-1997, "*Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments*". Copies may be ordered electronically at the following address: <http://www.ansi.org> or obtained by contacting the American National Standards Institute, 25 West 43rd Street Fourth Floor, New York, New York 10036, Phone: 212.642.4900, Fax: 212.398.0023.
6. "*Air Sampling Instruments*", American Conference of Governmental Industrial Hygienists, 7th Edition.
7. DOE G 441.1-7, "*Portable Monitoring Instrument Calibration Guide*", U.S. Department of Energy.
8. DOE G 441.1-8, "*Air Monitoring Guide*", U.S. Department of Energy".

Appendix P:

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 the section entitled ‘Training for Individuals Working In or Frequenting Restricted Areas’.

Materials Possessed Under a General License, or Received from a General Licensee

Individuals at your facility may receive and use material pursuant to a general license as authorized in **12VAC5-481-420** and **12VAC5-481-430**. Generally licensed materials are distributed by manufacturers authorized by VDH, the NRC or another Agreement State to distribute materials directly to the persons who will use them under a general license. Some common items include nickel-63 sources in electron capture detectors in certain gas chromatographs, tritium gas contained in self-luminous EXIT signs, calibration sources in liquid scintillation counters, and uranyl acetate used for staining electron microscope samples. You should develop a policy for how your institution will require responsible use and tracking of this material.

Generally licensed material may also be received when a general licensee transfers a generally licensed item to a specific license that is authorized to possess the material. However, when received under the authority of the specific licensee (your facility), the item must now be considered specifically licensed and should be tracked with other specifically licensed material.

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 **12VAC5-481-900**.
- 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). Check again 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.
- Notify the final carrier and, by telephone, and either electronic mail or facsimile, the Virginia Department of Health, when removable radioactive surface contamination exceeds the limits of **12VAC5-481-3080**; or external radiation levels exceed the limits of **12VAC5-481-3080**.

Sample Transfer Policy Statements

Internal Transfers

Licensed materials that may be transferred from one department or laboratory 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 institution to another without the approval of the RSO. Such transfers/shipments must be packaged and labeled in accordance with DOT, VDH, NRC, or U.S. Postal Service Regulations, whichever is applicable.

Gifts

On occasion, licensees may be offered or have donated licensed materials by other individuals as gifts (e.g., a retiring medical practitioner donating his cesium needles to the university medical center). All such gifts of radioactive materials must be transferred to the licensee and handled in accordance with VDH requirements and the conditions of the license. The RSO should approve the gift prior to the transfer.

References: DOE G 441.13-1, "*Sealed Radioactive Source Accountability and Control*", U.S. Department of Energy.

Appendix Q:

Methodology for Determining Public Dose

Doses to Members of the Public

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 materials do not result in doses greater than 0.1 mSv (10 mrem) Total Effective Dose Equivalent (TEDE).

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
- Licensed material in transportation or storage at the licensee's facility

BUT, 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.

In order to perform a dose assessment, the licensee 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 the facility. The licensee 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.
- Measurements of radionuclides in air and water effluent.

The method used to measure dose will depend on 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. An extremely conservative calculation would assume that the individual was continuously present 24 hours a day, 365 days a year, or an occupancy factor of 1 (see **Table 11**). 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, however, the licensee would rather choose a more realistic assumption of the individual's occupancy at the points of highest internal and external exposures, then the licensee may use the occupancy factors in **Table 11** or may calculate a specific occupancy factor by determining the likely fraction of time that the individual is present.

Table 11: 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.

Appendix R:

General Topics for Safe Use of Radioisotopes and Emergency Procedures

General Topics for Safe Use of Radioisotopes

Each laboratory or 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 laboratory coat or other 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.
- Secure all licensed material when it is not under the constant surveillance and immediate control of the user(s).

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 and include 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
- Performance of a dry run prior to performance of unfamiliar procedures, in order to preclude unexpected complications. In addition, it is recommended that the RSO be present during new procedures.
- 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 and include 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
- Performance of a dry run prior to performance of unfamiliar procedures, in order to preclude unexpected complications. In addition, it is recommended that the RSO be present during new procedures
- The use of eye protection for procedures that involve 10 millicuries or more.

Emergency Procedures

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
  - 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
  - Copy of ‘Emergency Procedures’
  - Clipboard with a copy of the Radioactive Spill Report Form for the facility
  - Pencil
  - Appropriate survey instruments, including batteries.

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident specific variables, such as the number of individuals affected; other hazards present; the likelihood of spread of contamination; and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides, the best spill procedure may be restricted access pending complete decay. The applicant should establish criteria for determining when the major spill procedure and minor spill procedure should be utilized.

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 the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Follow the instructions of the RSO and/or the RSO's 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 there is a potential for internal contamination.
- 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 the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Follow the instructions of the RSO and/or the RSO's 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 is suspected to have been ingested, inhaled, or absorbed through or injected under the skin.
  - 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 possible, unless it is determined that the room ventilation system needs to be used to clear the air for access purposes.
  - 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 the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
  - Follow the instructions of the RSO and/or the RSO's 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 is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document incident.
  - If necessary, notify VDH.

Minor Fires

- **Instructions to Workers**

- Immediately attempt to put out the fire by approved methods (e.g., fire extinguisher) if other 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 the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Follow the instructions of the RSO and/or the RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- **Reminders to RSO**

- Consult with fire safety officials to assure that there are no other possibilities of another fire starting.
  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.
- Determine cause and needed corrective actions; consider need for bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document incident.
- 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 the RSO and/or the RSO's 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.
- Follow the instructions of the RSO and/or the RSO's 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 fire-fighting 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, advise the firefighters not to enter potentially contaminated areas or areas where radioactive sources may be present 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 is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document incident.
- If necessary, notify VDH.

Copies of emergency procedures should be provided to all users. Post a current copy in each laboratory or other area where radioactive material is used.

Procedures for Collecting Bioassay Samples

In the event of an emergency where an individual may become 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. The following items should be considered in developing your procedures:

- the type of bioassay that must be performed (direct or indirect)
- the number of samples or data points to be collected
- the frequency of sampling (hourly, daily, weekly, once, etc.)
- the size of the sample to be collected (24-hour urine collection?)
- the ease/difficulty of sample collection
- the need for written instructions to be provided to the sample collector, who may be the contaminated individual.

Appendix S:

Radiation Surveys

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 (or for Type C broad scopes, the individual designated as responsible for the day-to-day operation of the radiation safety program) will ensure that he or she has sufficient training and experience to perform surveys independently.

Didactic 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
- Biological effects of radiation.

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

- Observing authorized personnel using survey equipment, collecting samples, and analyzing samples
- 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., cesium-137, cobalt-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.

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, laboratory furniture, and equipment
- After any spill or contamination event
- When procedures or processes have changed
- To evaluate contamination of users and the immediate work area, at the end of the day, when licensed material is used
- In unrestricted areas at frequencies consistent with the types and quantities of materials in use but not less frequently than quarterly
- 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 in an amount greater than or equal to 10% of the smallest annual limit on intake (ALI) (either the inhalation or ingestion ALI) listed for that radionuclide in **12VAC5-481-3690**. These surveys should be done at a frequency appropriate to the types and quantities of radioactive materials in use, but, at a minimum, quarterly. If amounts used are greater than or equal to the smallest ALI listed for that radionuclide in **12VAC5-481-3690**, detailed, documented, surveys should be performed at least monthly.

Table 12 contains suggested contamination survey frequency from NRC Regulatory Guide 8.23 (See **Tables 13, 14,** and **15** for alternate survey frequencies).

Table 12: Suggested Frequency of Contamination Surveys from NRC Regulatory Guide 8.23

Areas Where RAM Is Used	Frequency
Areas where > 7.4 MBq (200 µCi) is used at any one time	Weekly
Areas where < 7.4 MBq (200 µCi) is used at any one time	Monthly

Alternate Survey Frequency

Classification of Laboratories

Table 13: Survey Frequency Category

Group	Low	Medium	High
1	< 370 kBq (10 µCi)	370 kBq (10 µCi) to 37 MBq (1 mCi)	> 37 MBq (1 mCi)
2	< 37 MBq (1 mCi)	37 MBq (1 mCi) to 3.7 GBq (100 mCi)	> 3.7 GBq (100 mCi)
3	< 3.7 GBq (100 mCi)	3.7 GBq (100 mCi) to 370 GBq (10 Ci)	> 370 GBq (10 Ci)
4	< 370 GBq (10 Ci)	370 GBq (10 Ci) to 37 TBq (1000 Ci)	> 37 TBq (1000 Ci)

Proportional fractions are to be used for more than one isotope.

Table 14: Survey Frequency Category Modifiers

Modifying Factors	Factors
Simple storage	x 100
Very simple wet operations (e.g., preparation of aliquots of stock solutions)	x 10
Normal chemical operations (e.g., analysis, simple chemical preparations)	x 1
Complex wet operations (e.g., multiple operations, or operations with complex glass apparatus)	x 0.1
Simple dry operations (e.g., manipulation of powders) and work with volatile radioactive compounds	x 0.1
Exposure of non-occupational persons	x 0.1
Dry and dusty operations (e.g., grinding)	x 0.01

The object is to determine how often to survey the laboratory. To do this, multiply the activity range under LOW, MEDIUM, and HIGH survey frequency by the appropriate Modifying Factor to construct a new set of mCi ranges for LOW, MEDIUM, and HIGH survey frequency.

Survey Frequency:

- Low - Not less than once a month
- Medium - Not less than once per week
- High - Not less than once per normal working day.

Table 15: Isotope Groups

Group 1	Pb-210, Po-210, Ra-223, Ra-226, Ra-228, Ac-227, Th-227, Th-228, Th-230, Pa-231, U-230, U-232, U-233, U-234, Np-237, Pu-238, Pu-239, Pu-240, Pu-241, Pu-242, Am-241, Am-243, Cm-242, Cm-243, Cm-244, Cm-245, Cm-246, Cf-249, Cf-250, Cf-252
Group 2	Na-22, Cl-36, Ca-45, Sc-46, Mn-54, Co-56, Co-60, Sr-89, Sr-90, Y-91, Zr-95, Ru-106, Ag-110m, Cd-115m, In-114m, Sb-124, Sb-125, Te-127m, Te-129m, I-124, I-125, I-126, I-131, I-133, Cs-134, Cs-137, Ba-140, Ce-144, Eu-152, Eu-154, Tb-160, Tm-170, Hf-181, Ta-182, Ir-192, Tl-204, Bi-207, Bi-210, At-211, Pb-212, Ra-224, Ac-228, Pa-230, Th-234, U-236, Bk-249
Group 3	Be-7, C-14, F-18, Na-24, C1-38, Si-31, P-32, P-33, S-35, Ar-41, K-42, K-43, Ca-47, Sc-47, Sc-48, V-48, Cr-51, Mn-52, Mn-56, Fe-52, Fe-55, Fe-59, Co-57, Co-58, Ni-63, Ni-65, Cu-64, Zn-65, Zn-69m, Ga-72, As-73, As-74, As-76, As-77, Se-75, Br-82, Kr-85m, Kr-87, Rb-86, Sr-85, Sr-91, Y-90, Y-92, Y-93, Zr-97, Nb-93m, Nb-95, Mo-99, Tc-96, Tc-97m, Tc-97, Tc-99, Ru-97, Ru-103, Ru-105, Rh-105, Pd-103, Pd-109, Ag-105, Ag-111, Cd-109, Cd-115, In-115m, Sn-113, Sn-125, Sb-122, Te-125m, Te-127, Te-129, Te-131m, Te-132, I-130, I-132, I-134, I-135, Xe-135, Cs-131, Cs-136, Ba-131, La-140, Ce-141, Ce-143, Pr-142, Pr-143, Nd-147, Nd-149, Pm-147, Pm-149, Sm-151, Sm-153, Eu-152, Eu-155, Gd-153, Gd-159, Dy-165, Dy-166, Ho-166, Er-169, Er-171 (9.2 hr), Tm-171, Yb-175, Lu-177, W-181, W-185, W-187, Re-183, Re-186, Re-188, Os-185, Os-191, Os-193, Ir-190, Ir-194, Pt-l91, Pt-193, Pt-197, Au-196, Au-198, Au-l99, Hg-197, Hg-197m, Hg-203, Tl-200, Tl-201, Tl-202, Pb-203, Bi-206, Bi-212, Rn-220, Rn-222, Th-231, Pa-233, Np-239
Group 4	H-3, O-15, Ar-37, Co-58m, Ni-59, Zn-69, Ge-71, Kr-85, Sr-85m, Rb-87, Y-9lm, Zr-93, Nb-97, Tc-96m, Tc-99m, Rh-103m, In-113m, I-129, Xe-131m, Xe-133, Cs-134m, Cs-135, Sm-147, Re-187, Os-191m, Pt-193m, Pt-197m, Th-232, Th-Nat, U-235, U-238, U-Nat

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 16**.

Table 16. Acceptable Surface Contamination Levels

Nuclide[1]	Average[2, 3]	Maximum[2, 4]	Removable[2, 5]
I-125, I-129	1.7 Bq/100 cm^2 (100 dpm/100 cm^2)	5.0 Bq/100 cm^2 (300dpm/100cm^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/100 cm^2 (3,000 dpm/100 $cm^{2)}$	3.3 Bq/100 cm^2 (200 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)	6.7 Bq/100 cm^2 (1,000 dpm/100 cm^2)

[1] 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.
[2] 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.
[3] 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.
[4] The maximum contamination level applies to an area of not more than 100 cm^2.
[5] 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.

When equipment or facilities that are potentially contaminated are to be released for unrestricted use, the above table provides the maximum acceptable residual levels. To the extent practicable, it is appropriate to decontaminate to 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.

Survey Record Requirements

Each survey record should include the following:

- A diagram of the area surveyed
- A list of items and equipment surveyed
- Specific locations on the survey diagram where wipe test was taken
- Ambient radiation levels with appropriate units
- Contamination levels with appropriate units
- Make and model number of instruments used
- Background levels
- 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.

Air Monitoring in the Workplace

Air monitoring 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
- 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 can eliminate the 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 VDH 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 is 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, 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 concentrations found in column 1 of Table 2 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 V**.

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
- 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 radionuclides 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.

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
- Evidence of damage to or failure of a respiratory protective device.

References:

1. NRC Regulatory Guide 4.20, "*Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors*".
2. NRC Regulatory Guide 8.9, Revision 1, "*Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program*".
3. NRC Regulatory Guide 8.23, Revision 1, "*Radiation Safety Surveys at Medical Institutions*".
4. NRC Regulatory Guide 8.25, Revision 1, "*Air Sampling in the Workplace*".
5. NRC Regulatory Guide 8.32, "*Criteria for Establishing a Tritium Bioassay Program*".
6. NRC Regulatory Guide 8.37, "*ALARA Levels for Effluents from Materials Facilities*".
7. NRC NUREG-1400, "*Air Sampling in the Workplace*".
8. NRC NUREG/CR- 4884, "*Interpretation of Bioassay Measurements*".
9. ANSI N13.1 (1969), "*Document to Sampling Airborne Radioactive Materials in Nuclear Facilities*".
10. ANSI N13.30-1996, "*Performance Criteria for Radiobioassay*".
11. ANSI N42.18, "*Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents*".
12. NCRP Commentary No. 3, "*Screening Techniques for Determining Compliance with Environmental Standards*".
13. U.S. Department of Energy, DOE G 441.1-8, "*Air Monitoring Guide*".
14. U.S. Department of Energy, DOE G 441.1-3, "*Internal Dosimetry Program Guide*".
15. U.S. Department of Energy, DOE G 441.1-4, "*External Dosimetry Program Guide*".
16. U.S. Department of Energy, DOE G 441.1-2, "*Occupational ALARA Program Guide*".

Appendix T:

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 the frequency specified in **12VAC5-481-730** or 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, radionuclide, and activity.

- Use a survey meter to monitor exposure, if appropriate.
- 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 radionuclide and ensure that its calibration is current.
- Using the selected instrument, count, and record background count rate.
- Calculate efficiency of the detector. A sample calculation is shown below.
- Count the sample.

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 = becquerels

- 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 mCi) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly.
- Notify VDH.

Appendix U:

Transportation Requirements

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**, 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 packaging, 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 172.516, 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.
- 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.

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 Radionuclides** (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 quantify 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*: 1. highway only and no motor carrier transfers; *or* 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 nonbulk 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

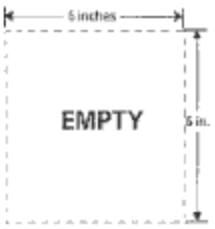
Labeling Packages (49 CFR 172.400-450)

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 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:
  - On four sides of the vehicle;
  - Visible from the direction they face, (for the front side of trucks, tractor-front, trailer, or both are authorized);
  - Clear of appurtenances and devices (e.g., ladders, pipes, tarpaulins);
  - At least 3 inches from any markings (such as advertisements) which may reduce placard's effectiveness;
  - Upright and on-point such that the words read horizontally;
  - In contrast with the background, or have a lined-border which contrasts with the background;
  - Such that dirt or water from the transport vehicle's wheels will not strike them;
  - 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 a 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 for any vehicle containing a 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)

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 (§173.435)	1 rem/hr at 3 m, un-shielded (§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. This 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
" 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
	α: 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: • Contamination levels at beginning of transport must be below the basic limits. • 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: • 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). • Exterior of vehicle must be conspicuously stenciled, "For Radioactive Materials Use Only" in letters at least 76 mm (3 inches) high, on both sides. • 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 offeror at the earliest practicable moment after incident.

Excepted packages

Packages that conform to the conditions and limitations specified in 49 CFR 173.424 must maintain a label, during shipping, only including the appropriate UN number. Training must also be provided to all individuals who may handle or transport this material.

Appendix V:

Sample Waste Management **Procedures**

General Guidelines

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal into ordinary, non-radioactive waste streams. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
2. Remind workers that non-radioactive waste such as leftover reagents, boxes, and packaging material should not be mixed with radioactive waste.
3. 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.
4. 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.
5. Waste management program should include waste handling procedures for the users within their laboratories or assigned areas, and for waste handlers who may collect waste from areas of use to bring to the storage area for eventual disposal.
6. 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.

Sample Procedure for Disposal by Decay-in-Storage (DIS)

Applicants should assure that adequate space and facilities are available for the storage of waste for DIS. Licensees can minimize the need for storage space if the waste is segregated according to physical half-life.

1) Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.
2) Short-lived waste should be segregated from long-lived waste.
3) Waste should be stored in suitable well-marked containers and the containers should provide adequate shielding.
4) Liquid and solid wastes must be stored separately.
5) When the container is full, it should be sealed. The sealed container should be identified with a label affixed or attached to it.
6) The identification label should include the date when the container was sealed, the longest-lived radioisotope in the container, total activity, date when ten half-lives of the longest-lived radioisotope will have transpired, and the initials of the individual who sealed the container. The container may be transferred to the DIS area. When large quantities are held for DIS, sufficient quantities may be present even after 10 half-lives that individuals performing surveys should be aware of the potential for measurable radiation.
7) The contents of the container should be allowed to decay for at least ten half-lives of the longest-lived radioisotope in the container.
8) Prior to disposal as ordinary trash, each container should be monitored as follows:
   a) Check the radiation detection survey meter for proper operation.
   b) Survey the contents of each container in a low background area.
   c) Remove any shielding from around the container.
   d) Monitor all surfaces of the container.
   e) 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).

f) If the surveys indicate residual radioactivity, return the container to DIS area and contact the RSO for further instructions.

9) 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; and that the waste is incinerated, not placed in a landfill; and the waste disposal firm is cautioned not to open the container prior to incineration.

Sample Procedure for Disposal of Liquids into Sanitary Sewerage

1) Confirm that the sewer system is a public system, not a private sanitary sewer, septic system, or leach field.
2) Confirm that the liquid waste being discharged is soluble (or is biological material that is readily dispersible) in water.
3) 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**.
4) 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** (records for individual users/laboratories).
5) If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit in **12VAC5-481-3690** must not exceed unity.
6) Total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 185 GBq (5 Ci) of H-3 (tritium), 37 GBq (1 Ci) of C-14, and 37 GBq (1 Ci) of all other radioisotopes combined.
7) 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.
8) Liquid waste should be discharged only via designated sinks or toilets.
9) Discharge liquid waste slowly to minimize splashing with water running, to be sure that the material moves out of the sink and into the sewer system.
10) Survey the sink and surrounding work surfaces to confirm that no residual material or contamination remained in the sink or on work surfaces. Decontaminate as appropriate.
11) Decontaminate all areas or surfaces if found to be contaminated.
12) For all releases to the sanitary sewer from the licensed facility, maintain records of each radioisotope and its quantity and concentration that is released into the sewer system that demonstrate compliance with the regulatory limits for total quantity released and concentrations released by the licensed facility.

Sample 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 that requires specific VDH approval for incineration, please provide the following information:

1. Describe the training and experience of the person who will be responsible for the on-site and day-to-day supervision of incinerator operations.
2. 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.
3. 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.
4. 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 the ash residue.
5. Describe the recordkeeping procedures for the waste incineration program. Records must be adequate to document all receipts, incinerations, environmental releases of effluents, and any disposals of ash generated in the incineration process. These records must be maintained in the same units as applicable rules.
6. Describe the characteristics of the incinerator and 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.
7. State how the concentration of radionuclides released, both as airborne effluent and as any liquid effluent from scrubbers, condensers, or associated systems, will be measured or otherwise determined. Describe any stack monitoring that is planned.
8. Provide a copy of the written safety analysis that demonstrates 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'**.
9. Provide a written commitment that the applicant has coordinated with appropriate state and local authorities and that such permits and other authorizations, as may be necessary, have been obtained.
10. 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 regulatory limits for environmental releases of radioactivity will not be exceeded. The applicant must describe how any ash generated exceeding regulatory limits will be disposed of.

Compaction of Waste

The following information should be provided from licensees who propose to compact waste:

1. Describe the compactor to demonstrate that it is adequately designed and manufactured to safely compact the type and quantity of waste generated during licensed operations (e.g., manufacturer's specifications, annotated sketches, photographs, etc.).
2. Describe the type, quantities, and concentrations of waste to be compacted.

3. Provide an analysis of the potential for airborne release of radioactive material during compaction activities.
4. 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.
5. Discuss the methods used to monitor worker breathing zones and/or exhaust systems.
6. Discuss the types and frequencies of surveys that will be performed for contamination control in the compactor area.
7. Discuss the instruction provided to compactor operators, including instructions for protective clothing; checks for proper functioning of equipment; method of handling un-compacted waste; and examining containers for defects.

Appendix W

12VAC5-481-451: Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material; and 12VAC5-481-1151: Reporting of Transaction Involving Nationally Tracked Sources

12VAC5-481-451

This appendix provides guidance to a licensee or applicant for the implementation of **12VAC5-481-451**, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." **12VAC5-481-451** was revised in order to make it compatible with NRC regulation of 10 CFR Part 37. NRC revised 10 CFR Part 37 in March 2013 and the Agreement States were required to implement compatible regulations by March of 2016.

12VAC5-481-451 became effective on March 8, 2016. New definitions such as reviewing official, security zone, safe heaven, telemetric position monitoring system, movement control center, etc., are included in the revised regulation. The requirements under this regulation provide reasonable assurance of the security of category 1 or category 2 quantities of radioactive material by protecting these materials from theft or diversion.

The table below lists the Category 1 and Category 2 quantities of radioactive materials:

Radionuclide			Category 1 (TBq)[1,2]	Category 1 (Ci)[1,2]	Category 2 (TBq)[1,2]	Category 2 (Ci)[1,2]
Am-241			60	1,620	0.6	16.2
Am-241/Be			60	1,620	0.6	16.2
Cf-252			20	540	0.2	5.4
Cm-244			50	1,350	0.5	13.5
Co-60			30	810	0.3	8.1
Cs-137			100	2,700	1	27
Gd-153			1,000	27,000	10	270
Ir-192			80	2,160	0.8	21.6
Pm-147			40,000	1,080,000	400	10,800
Pu-238			60	1,620	0.6	16.2
Pu-239/Be			60	1,620	0.6	16.2
Ra-226			40	1,080	0.4	10.8
Se-75			200	5,400	2	54
Sr-90 (Y-90)			1,000	27,000	10	270
Tm-170			20,000	540,000	200	5,400
Yb-169			300	8,100	3	81
Combinations of radioactive materials listed above[3]					See footnote[4] below	

[1]The aggregate activity of multiple, collocated sources of the same radionuclides should be included when the total activity equals or exceeds the Category 1 or Category 2 threshold.

[2]The primary values used for compliance are TBq. The curie (Ci) values are rounded to two significant figures for informational purposes only.

[3]Radioactive materials are to be considered aggregated or collocated if breaching a common physical barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material.

[4]If several radionuclides are aggregated, the sum of the ratios of the activity of each source, i of radionuclide, n, A (i,n), to the Category 1 or Category 2 threshold for radionuclide n, Q_n, listed for that radionuclide equals or exceeds one. [(aggregated source activity for radionuclide A) / (quantities of concern for radionuclide A)] + [(aggregated source activity for radionuclide B) / (quantities of concern for radionuclide B)] + etc…. ≥ 1

12VAC5-481-451 has the following four main Subsections:

Subsection A, requires licensee to establish a physical protection program.

Subsection B, requires licensees to establish background investigation and an access authorization program to ensure that individuals who have unescorted access to Category 1 and 2 quantities of radioactive material and reviewing officials are trustworthy and reliable.

Subsection C, requires licensees to establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to any actual or attempted unauthorized access to Category 1 or Category 2 quantities of radioactive material in use or storage.

Subsection D, requires licensees to provide for physical protection of Category 1 or Category 2 quantity of radioactive materials in transit. These requirements apply to a person delivering material to a carrier for transport, as well as cases in which the person transports material. If licensees intend to transfer category 1 or category 2 quantities of radioactive material to a licensee of the agency, the NRC, or another agreement state, then prior to conducting such transfer they are required to verify with the NRC's license verification system or the license-issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

NRC Guidance Documents

Licensees or applicants should refer to NRC NUREG 2155 and NUREG 2166 for detailed guidance in implementing the physical protection requirements set forth under 12VAc5-481-451.

NUREG 2155 and NUREG 2166 are found in the following link:
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/

12VAC5-481-1151: Reports of Transactions Involving Nationally Tracked Sources

Nationally tracked source is a sealed source containing a quantity equal to or greater than category 1 or category 2 levels of any radioactive materials listed in **12VAC5-481-3780**. If licensees possess, ship, or receive quantities of material exceeding Category 1 or category 2, then they must also comply with requirements specific to Category 1 or category 2 quantities.

The regulations in **12VAC5-481-1151** require that each licensee that manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit an NSTS report