
Commonwealth of Virginia
Radiation Protection Regulatory Guide



**Guidance for Academic, Research and
Development, and other Licenses of
Limited Scope**

EPI-720 (F)

Virginia Department of Health
Radioactive Materials Program
109 Governor Street, Room 730
Richmond, VA 23219
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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 **12 VAC 5-481 ‘Virginia Radiation Protection Regulations’**, to delineate techniques used by the staff in evaluating past specific problems or postulated accidents, and to provide guidance to applicants, licensees, or registrants. VAREGS are not substitutes for **12 VAC 5-481 ‘Virginia Radiation Protection Regulations’**; therefore, compliance with them is not required. Methods and solutions different from those set forth in this guide will be acceptable if they provide a basis for the Virginia Department of Health (VDH), Radioactive Materials Program, to determine if a radiation protection program meets the current rule and protects health and safety.

Comments and suggestions for improvements in this VAREG are encouraged 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, Radiological Health Program, 109 Governor Street, Room 730, Richmond, VA 23219. This guide is also available on our website: <http://www.vdh.virginia.gov/rad/RHP-Index.asp>.

This VAREG, ‘Guidance for Academic Research, Development, and other Licenses of Limited Scope’ has been developed to streamline the application process for a Academic Research & Development and other Licenses of Limited Scope License. A copy of the VDH Form, ‘Application for Radioactive Material License Authorizing the Use of Radioactive Material for Research and Development, and other Licenses of Limited Scope’ is located in Appendix A of this guide.

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

It typically takes 60-90 days for a license to be processed and issued if the application is complete. When submitting the application be sure to include the appropriate application fee listed in **12 VAC 5-490.**

In summary, the applicant will need to do the following to submit an application for Academic, Research & Development and other Licenses of Limited Scope License:

- Use this regulatory guide to prepare the VDH Form, ‘Application for Radioactive Material License for Academic, Research and Development, and other Licenses of Limited Scope’ (**Appendix A**).
- Complete VDH Form, ‘Application for Radioactive Material License for Research and Development, and other Licenses of Limited Scope’ (**Appendix A**). See ‘Contents of Application’ of the guide for additional information.

- Include any additional attachments.

All supplemental pages should be submitted 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.
- Submit an original signed application along with attachments (if any).
- Submit the application fee (for new licenses only).
- Retain one copy of the license application and attachments (if any) for your future reference. You will need this information because the license will require that radioactive material be possessed and used in accordance with statements, representation, and procedures provided in the application and supporting documentation.

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

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ABBREVIATIONS

ALARA	as low as is reasonably achievable
ALI	annual limit on intake
bkg	background
Bq	Becquerel
CFR	Code of Federal Regulations
Ci	Curie
cc	centimeter cubed
cm ²	centimeter squared
cpm	counts per minute
DOT	United States Department of Transportation
dpm	disintegrations per minute
GM	Geiger-Mueller
IN	Information Notice
mCi	millicurie
mR	milliroentgen
mrem	millirem
mSv	millisievert
NIST	National Institute of Standards and Technology
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OSL	optically stimulated luminescence dosimeters
RG	Regulatory Guide
RSO	Radiation Safety Officer
SI	International System of Units (abbreviated SI from the French Le Système 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
%	percent

PURPOSE OF GUIDE

This document provides guidance to an applicant in preparing a license application for Academic, Research and Development and other Licenses of Limited Scope. It also provides guidance on VDH's criteria for evaluating a Academic, Research and Development and other Licenses of Limited Scope license application. It is not intended to address the commercial aspects of manufacturing, distribution, and service of sources in devices.

This guide describes the information needed to complete VDH Form, 'Application for Radioactive Material License Authorizing the Use of Radioactive Material for Academic Research and Development and other Licenses of Limited Scope' (**Appendix A**).

The format for each item number in this guide is as follows:

- **Rule** – references the requirements of 12 VAC 5-481 '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; and
- **Response from Applicant** – shows the appropriate item on the application and provides: response(s), offers the option of an alternative response, or indicates that no response is needed on that topic.

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 in accordance with agency guidelines. Submission of incomplete or inadequate information will result in delays in the approval process for the license. Additional information will be requested when necessary to ensure that an adequate radiation safety program has been established. Such requests for additional information will delay completion of the application's review and may be avoided by a thorough study of the rule and these instructions prior to submitting the application. .

12 VAC 5-481 ‘Virginia Radiation Protection Regulations’ requires the applicant and/or licensee to develop, document, and implement procedures that will ensure compliance with the rule. The appendices describe radiation protection procedures. Each applicant should read the rule and procedures carefully and then decide if the procedure addresses specific radiation protection program needs at the applicant’s facility. Applicants may adopt a procedure included in this VAREG or they may develop their own procedures to comply with the applicable rule.

In this guide, “dose” or “radiation dose” means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent (TEDE). These terms are defined in the **12 VAC 5-481-10**. 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 **12 VAC 5-481 ‘Radiation Protection Regulations’, Part IV ‘Standards for Protection Against Radiation’**, sets dose limits in terms of rem, not rad or roentgen. 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 and is modeled on the Nuclear Regulatory Commission’s (NRC) NUREG 1556, Volume 11. The VAREG shows the requirements in terms of the **12 VAC 5-481 “Virginia Radiation Protection Regulation”** and provides a user-friendly format to assist with the preparation of an Academic, Research and Development, and other Licenses of Limited Scope 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 Authorizing the Use of Sealed Sources in Research & Development” (Appendix A). VDH expects licensees to provide requested information on specific aspects of their proposed radiation protection program in attachments to the application. When necessary, VDH may ask the applicant for additional information to gain reasonable assurance that an adequate radiation protection program has been established.

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

- Statements, representations, and procedures contained in the application and in correspondence with VDH;
- Terms and conditions of the license; and
- **12 VAC 5-481 ‘Virginia Radiation Protection Regulations’.**

THE ‘AS LOW AS IS REASONABLY ACHIEVABLE (ALARA)’ CONCEPT

12 VAC 5-481-630, Radiation protection programs, states that “*each licensee shall develop, document, and implement a radiation protection program commensurate commensurate with the scope and extent of licensed activities*” and “*the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are...ALARA.*” This section also requires that licensees review the content of the radiation protection program and its implementation annually.

Information directly related to radiation protection standards in **12 VAC 5-481 ‘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 the 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 VDH or NRC regulatory requirements, as appropriate. The following table lists examples of regulatory authority.

Table 1: Who Regulates the Activity?

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

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

MANAGEMENT RESPONSIBILITIES

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

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

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

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

APPLICABLE RULE

It is the applicant's or licensee's responsibility to obtain, read, and follow **12 VAC 5-481 'Virginia Radiation Protection Regulations'**.

The following parts of **12 VAC 5-481 'Virginia Radiation Protection Regulations'** contain requirements applicable to Academic, Research and Development, and other Licenses of Limited 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"

Requests for single copies of the above documents (which may be reproduced) can be made in writing to Virginia Department of Health, Radiological Health 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/rad/RHP-Index.asp>.

HOW TO FILE

Applicants for a materials license should do the following:

- Be sure to use the current guidance from VDH in preparing an application.
- Complete VDH Form 'Application for Radioactive Material License Authorizing the Use of Radioactive Material for Academic Research and Development and other Licenses of Limited 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.
- Submit an original, signed application.
- Retain one copy of the license application for your future reference.

Deviations from the suggested wording of certain 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 **12 VAC 5-481 '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 or license amendment request. Refer to **12 VAC 5-490** to determine the amount of the fee. VDH will not issue the new license prior to fee receipt. Once technical review has begun, no fees will be refunded. Application fees will be charged regardless of VDH's disposition of an application or the withdrawal of an application.

Licensees are also subject to annual fees; refer to **12 VAC 5-490**.

Direct all questions about VDH's fees or completion of **Item 11** of VDH Form 'Application for Radioactive Material License Authorizing the Use of Radioactive Material for Academic Research and Development and other Licenses of Limited Scope' (**Appendix A**) to: Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, Virginia 23218 or (804) 864-8150.

CONTENTS OF APPLICATION

Item 1: License Action Type

On the application check the appropriate box and list the license number for renewals and amendments.

Response from Applicant:

Item 1 Type Of Application (Check one box) <input type="checkbox"/> New License <input type="checkbox"/> Renewal 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.

Response from Applicant:

Item 2 Name And Mailing Address Of Applicant:
Applicant's Telephone Number (Include area code):

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

Timely Notification of Change of Ownership or Control

Rule: 12 VAC 5-481-490 B

Criteria: Licensees must provide full information and obtain the VDH's **written consent prior** to transferring ownership or control of the license (commonly referred to as "transferring the license").

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

- Radioactive materials are possessed, used, or controlled only by persons who have valid VDH, the NRC, or another Agreement State licenses;
- 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 disposition of records and licensed material; and

- Public health and safety are not compromised by the use of such materials.

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

Notification of Bankruptcy Proceedings

Rule: 12 VAC 5-481-490 E & F

Criteria: 12 VAC 5-481-490 E 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(14)) 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(a)) of the licensee." The licensee shall notify VDH in writing within 10 days of filing of a voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify VDH in writing, identifying the bankruptcy court in which the petition was filed and the date of filing.

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 immediately notify VDH of the filing of a bankruptcy petition.

Item 3: Person to Contact Regarding Application

This person is typically the proposed RSO, unless the applicant has named a different person as the contact. The agency will contact this individual if there are questions about the application. Notify the agency if the contact person or their telephone number has changed so that the agency can contact the applicant or licensee in the future with questions, concerns or information. This notice is for "information only" and does not require a license amendment or a fee.

Response from Applicant:

Item 3 Person To Contact Regarding Application:
Contact's Telephone Number (Include area code):

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

Rule: 12 VAC 5-481-450 & 490 C

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

Discussion: Specify the street address, or other descriptive address (such as on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234), city and zip code for each permanent storage or use facility and field station. **A Post Office Box address is not acceptable** because the agency needs a specific address to allow a

VDH inspector to find the use and/or storage location.

A VDH-approved license amendment is required before receiving, using and storing licensed material at an address or location not included with the application or already listed on the license.

Obtaining 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).

As discussed later under 'Financial Assurance and Record Keeping for Decommissioning,' licensees must maintain permanent records describing 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.

Response from Applicant:

Item 4 Address(es) Where Radioactive Material Will Be Used Or Possessed (Do not use Post Office Box)	
Address	Telephone Number (Include area code)
Address	Telephone Number (Include area code)
Address	Telephone Number (Include area code)
Is radioactive material used at locations for field studies or other off-site locations? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If yes, please attach an additional sheet(s) with the locations address(es) and a list of activities to be conducted at each location.	

Item 5: Radiation Safety Officer (RSO)

Rule: 12 VAC 5-481-450 A 1, & 630 and 12 VAC 5-481-1700, 1750, 1780 & 1790

Criteria: RSOs must have training and specific experience, with the types and quantities of licensed material to be authorized on the license.

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

The agency believes that to demonstrate adequate training and experience, the RSO should have: (1) as a minimum, a college degree at the bachelor level, or equivalent training and experience in physical, chemical,

biological sciences, or engineering; and (2) training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- Radiation Protection Principles;
- Characteristics of Ionizing Radiation;
- Units of Radiation Dose and Quantities;
- Radiation Detection Instrumentation;
- Biological Hazards of Exposure to Radiation (appropriate to types and forms of radioactive material to be used);
- **12 VAC 5-481, ‘Virginia Radiation Protection Regulations’**; and
- Hands-on use of radioactive materials.

The amount of training and experience needed will depend upon the type, form, quantity and proposed use of the licensed material requested. Ultimately, the proposed RSO's training and experience should be sufficient to identify and control the anticipated radiation hazards. In addition, the RSO designee should have obtained the above training in a formal course designed for RSOs presented by an academic institution, commercial radiation safety consulting company, or a professional organization of radiation protection experts.

Response from Applicant:

RADIATION SAFETY OFFICER (RSO)	
Item 5 Radiation Safety Officer (RSO) (Attach evidence of training and experience and check one box)	
Name – Radiation Safety Officer	Telephone Number (Include area code)
<input type="checkbox"/> Before obtaining radioactive material, the proposed RSO will have successfully completed one of the training courses described in the Criteria section titled “Individual(s) Responsible for Radiation Safety Program and Their Training and Experience- in VAREG ‘Guidance for Academic, Research and Development, and other Licenses of Limited Scope’. <div style="text-align: center;">AND</div> Before being named as the RSO, future RSOs will have successfully completed one of the training courses described in the Criteria section titled “ Individual(s) Responsible for Radiation Safety Program and Their Training and Experience- Radiation Safety Officer” in VAREG “Guidance for Academic, Research and Development and Other Licenses of Limited Scope.”	
<input type="checkbox"/> Alternative information demonstrating that the proposed RSO is qualified by training and experience is attached.	

Note: It is important to notify the agency, as soon as possible, of changes in the designation of the RSO. The name and qualifications of the replacement RSO must be submitted to the agency as part of an amendment request.

Item 6: Authorized Users & Training

Rule: 12 VAC 5-481-450 A 1; 12 VAC 5-481-1750-1780 & 2270

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

Discussion: An AU (also known as "principal investigator") is a person whose training and experience have been reviewed and approved by VDH, who is named on the license, and who uses or directly supervises the use of

licensed material. The AU's primary responsibility is to ensure that radioactive materials used in his or her particular lab or area are used safely and according to regulatory requirements. The AU is also responsible to ensure that procedures and engineering controls are used to keep occupational doses and doses to members of the public ALARA.

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

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

- Radiation Protection Principles;
- Characteristics of Ionizing Radiation;
- Units of Radiation Dose and Quantities;
- Radiation Detection Instrumentation;
- Biological Hazards of Exposure to Radiation (appropriate to the types and forms of radioactive material to be used); and
- Hands-on Use of Radioactive Materials.

The amount of training and experience needed will depend upon the type, form, quantity and proposed use of the licensed material requested, but it should cover the subjects stated.

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

Applicants must name at least one individual who is qualified to use the requested licensed materials. In general, AUs must demonstrate training and experience with the type and quantity of material that they propose to use. For example, someone with training and experience only with sealed radioactive sources may not be qualified to use or supervise the use of unsealed licensed material. In addition, someone with experience using only trace quantities may not understand the risks of working with much larger (e.g., 10 or 100 times larger) quantities of the same substance. Applicants should pay particular attention to the type of radiation involved. For example, someone experienced with gamma emitters may not have appropriate experience for high-energy beta emitters.

Response from Applicant:

<p>Item 6. Authorized Users (Check both boxes)</p> <p><input type="checkbox"/> We will attach a list of each proposed authorized user with the types and quantities of licensed material to be used.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Information is attached demonstrating that each proposed authorized user is qualified by training and experience to use the requested licensed material.</p>

Item 7: Training for Individuals Working in or Frequenting Restricted Areas (Occupationally Exposed Individuals and Ancillary Personnel)

Rule: 12 VAC 5-481-450 A 1; 12 VAC 5-481-2270 A.

Criteria: Individuals whose assigned duties involve exposure to radiation and/or radioactive material (from both licensed and unlicensed sources), and in the course of their employment are likely to receive in a year an occupational dose of radiation greater than 1 mSv (100 mrem), must receive instruction commensurate with their duties and responsibilities, as required by 12 VAC 5-481-2270

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

Licensees should not assume that safety instruction has been adequately covered by prior employment or academic training. Site-specific training should be provided for all individuals. Particular attention should be given to persons performing work with radioactive materials that may require special procedures, such as hot cell work, waste processing, and animal handling. Also, ancillary personnel (e.g., clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and the appropriate precautions. The licensee should assess each individual's involvement with licensed material and cover each applicable subject appropriately.

Training may be in the form of lecture, demonstrations, videotape, or self-study, and should emphasize practical subjects important to the safe use of licensed material. The guidance in **Appendix J** may be used to develop a training program. The program should consider both the topics pertinent for each group of workers and the method and frequency of training.

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

Response from Applicant:

<p>Item 7 Training For Individuals Working In Or Frequenting Restricted Areas (Occupationally exposed individuals and ancillary personnel) (Check box)</p> <p><input type="checkbox"/> A description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors and the method and frequency of training is attached.</p>
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Item 8: Radioactive Material

Rule: 12 VAC 5-481-440 F-G & 450; 12 VAC 5-481-1670-1680, 1740, & 1840

Criteria: An application for a license will be approved if the requirements of 12 VAC 5-481-440 F are met. In addition, licensees will be authorized to possess and use only those sealed sources and devices that are specifically approved or registered by the NRC or another Agreement State.

Discussion: Each authorized radioisotope is listed on the VDH license by its element name, chemical and/or physical form, and the maximum possession limit. **Table 2** below shows the type of radioactive material covered by this guide.

Table 2: Types of Radioactive Material

Type of Material	Covered by this Guide	Examples
Radioactive Material	Yes	H-3, C-14, I-131, I-125, S-35, P-32, P-33, Ca-45, Ni-63, Cd-109, Cs-137
Source material	No	U, Th
Special nuclear material	No	Pu, etc.
Naturally occurring radioisotopes	No	Unsealed Ra-226
Accelerator-produced radioisotopes	Yes	Co-57, Na-22, Tl-201, Ga-67

The applicant should list each requested radioisotope by its element name and its mass number [e.g., Carbon-14 (C-14)] in **Item 8**. It is necessary to specify whether the material will be acquired and used in unsealed or sealed form. The name of the specific chemical compound that contains the radioisotope is not required. For volatile radioactive material, however, it is necessary to specify whether the requested radioisotope will be acquired in free (volatile) or bound (non-volatile) form, because additional safety precautions are required when handling and using free form volatile material. For example, when requesting authorization to use tritium (H-3) or iodine-125 (I-125), the applicant must specify whether the material will be acquired in free form or bound form. If a radioisotope will be acquired in both free and bound forms, then separate possession limits for each form must be specified.

Applicants requesting an authorization to use volatile radioactive material must provide appropriate facilities, engineering controls, and radiation safety procedures for handling of such material.

If you plan to possess radioactive materials in excess of the quantities listed in **12 VAC 5-481-3740**, then you must provide with the application either:

- 1) an evaluation showing that the maximum off-site dose due to a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid, or
- 2) an emergency response plan for responding to the release in accordance with the criteria listed in **12 VAC 5-481-440 G 2**.

The anticipated possession limit in MBq (millicuries) or GBq (curies) for each radioisotope should also be specified. Possession limits must cover the total anticipated inventory, including licensed material in storage and waste, and should be commensurate with the applicant's needs and facilities for safe handling. Applicants should review the requirements for submitting a certification for financial assurance for decommissioning before specifying possession limits of any radioisotope with a half-life greater than 120 days. These requirements are discussed in the section titled 'Financial Assurance and Record Keeping for Decommissioning'.

Before proceeding further, applicants should determine if their proposed uses of licensed material are in excess of the quantities specified in **12 VAC 5-481-3730**. It is not necessary to submit an application to VDH for quantities of radioactive material that are covered by the exemption in **12 VAC 5-481-390** provided that they are received from entities that are licensed to distribute them. Similarly, certain prepackaged units (typically called kits) containing radioactive material for conducting "*in vitro*" clinical or laboratory tests, are distributed to persons who are generally licensed. Rules related to possession and use of such prepackaged kits under a general license are stated in **12 VAC 5-481-430 G**. Persons eligible for this general license are limited to physicians, veterinarians in the practice of veterinary medicine, clinical laboratories, and hospitals; however, these persons are required to register with VDH before acquiring or using these units, unless they have a VDH license under **12 VAC 5-481 'Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts'**.

Certain devices containing sealed sources of radioactive material, such as Electron Capture Devices in Gas Chromatographs (GCs), are authorized by VDH, the NRC or another Agreement State for distribution to persons

who are generally licensed as well as to persons who are specifically licensed. Generally licensed devices can be acquired by the users without obtaining a specific license from VDH. Regulatory requirements for such devices possessed under a general license are stated in **12 VAC 5-481-430 B**. Distributors of such devices must provide users with appropriate information related to the acquisition, use, and transfer of these generally licensed devices. Alternatively, GCs may be authorized on an ARDL specific license. **Appendix D** information shall be submitted in support of such a request.

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

NRC or an Agreement State performs a safety evaluation before authorizing a manufacturer or distributor to distribute to specific licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) Registration Certificate. Licensees can continue to use these gauges that are specifically listed on their licenses.

Response from Applicant

Item 8 Radioactive Material (Attach additional pages if necessary)

UNSEALED SOURCES				
Radioisotope				
Chemical/Physical Form				
Maximum Possession Limit				
Proposed Use				

SEALED SOURCES				
Radioisotope				
Chemical/Physical Form	SEALED SOURCE	SEALED SOURCE	SEALED SOURCE	SEALED SOURCE
Sealed Source Manufacturer or Distributor and Model Number				
Device Manufacturer or Distributor and Model Number				
Maximum Possession Limit				
Proposed Use				

Purpose(s) for Which Licensed Material Will Be Used

Rule: 12 VAC 5-481-10, 440, 450, & 490

Criteria: The applicant must specify the purpose of use for each sealed and/or unsealed radionuclide requested. All sealed sources and devices containing licensed material shall be used only for the purpose for which they are designed, and according to manufacturer’s (distributor’s) instructions and recommendations for use as specified in the SSD Registration Certificate.

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

Research and development, as defined in 12 VAC 5-481-10, does not include research involving the use of licensed material in or on humans. Applicants intending to use licensed materials for medical research involving humans must be authorized to do so pursuant to a license issued under 12 VAC 5-481 ‘Radiation Protection Regulations’, Part VII ‘Use of Radionuclides in the Healing Arts’, and should refer to VAREG EPI 720 G, ‘Guidance for Medical Use of Radioactive Materials’.

Applicants may use the format given in **Table 3** to provide the requested information.

Table 3: Sample Format for Providing Information About Requested Radioisotopes

Radioisotope	Chemical/Physical Form	Maximum Possession Limit	Proposed Use
H-3	Unbound/volatile	100 millicuries	Labeling of compounds
H-3	Bound/non-volatile	100 millicuries	In vitro studies; studies in small lab animals
P-32	Any	30 millicuries	In vitro studies; labeling of compounds
I-125	Unbound/volatile	30 millicuries	Protein iodination
I-125	Bound/non-volatile	50 millicuries	In vitro studies; studies in small lab animals; calibration of instruments
Cs-137	Sealed source, Mfg. name/ model number	20 millicuries	Calibration of instruments

Applicants should clearly specify if the licensed material will be used in animal studies and/or tracer studies. Use of licensed material in animals may be in research studies, or by veterinarians for diagnostic and therapeutic purposes. Applicants should also state whether the studies will be limited to small animals (e.g., rats, mice) or may also include larger animals (e.g., pigs, dogs, horses). Similarly, the veterinary use should specify whether the material will be used in pets (cats, dogs) or in farm animals (cattle, horses, pigs). **Appendix H** provides guidance for developing radiation safety procedures for these studies and procedures.

Applicants should note that authorization from VDH to use licensed material in animal and/or tracer studies does not relieve them of their responsibilities to comply with any other applicable Federal, state or local regulatory requirements.

Financial Assurance and Record Keeping for Decommissioning

Rule: 12 VAC 5-481-450 C

Criteria: A licensee authorized to possess licensed material in excess of the limits specified in **12 VAC 5-481-450 C 1** must submit a decommissioning funding plan (DFP) or provide a certification of financial assurance (F/A) for decommissioning. All licensees are required to maintain records of information important to the decommissioning of the facility in an identified location until the site is released for unrestricted use. Licensees must transfer these records either to the new licensee before licensed activities are transferred or assigned in accordance with **12 VAC 5-481-490 B** or to VDH before the license is terminated.

Discussion: The agency wants to ensure that decommissioning will be carried out with minimum impact on the public, occupational health and safety, and the environment. There are two parts to this rule: financial assurance that applies to some licensees, and record keeping that applies to all licensees.

VDH requirements for F/A and/or a DFP are designed to provide reasonable assurance that the technical and environmental components of decommissioning are carried out and unrestricted use of the facilities is possible at the conclusion and/or termination of licensed activities. The agency wants to ensure that decommissioning will be carried out with minimum impact on public and occupational health and safety and on the environment. These requirements, if applicable, specify that a licensee either set aside funds for decommissioning activities or provide a guarantee through a third party that funds will be available. Applicants are required to submit an F/A and/or a DFP when the possession of radioactive material of half-life (T1/2) greater than 120 days exceeds certain limits. Criteria for determining whether an applicant is required to submit a DFP and/or an F/A (or neither) are stated in **12 VAC 5-481-450 C 4**.

Table 4 is a partial list of radioisotopes of T1/2 > 120 days with their corresponding limits in excess of which an F/A or a DFP is required; however, it is the agency's experience that most ARDL licensees use only a few of these radioisotopes and that the most frequently used radioisotopes are hydrogen-3 (H-3), carbon-14 (C-14), chlorine-36 (Cl-36), and calcium-45 (Ca-45) in unsealed form. The amounts of such radioisotopes required by ARDL licensees rarely exceed the limits that require submitting a DFP or an F/A. See **Table 4** for possession limits and guidance for submitting either a DFP or an F/A. Radioisotopes of T1/2 > 120 days are listed in column 1. Column 2 lists the corresponding possession limits of radioisotopes in unsealed form requiring an F/A. Column 3 lists the corresponding possession limits of radioisotopes in unsealed form requiring the submittal of a DFP. These limits apply when only one of these radioisotopes is possessed.

Applicants can use the data from **Table 4** below or the method given in **Appendix G** to determine if an F/A is required and the amount that is required when more than one of these radioisotopes is requested. Most of the ARDL licensees use a small number of these radioisotopes, and in many cases the use is limited to only H-3 and C-14. Such licensees may be able to adjust the amounts of these radioisotopes so that the financial assurance requirement is not applicable.

Table 4: Commonly Used Unsealed Licensed Material Requiring Financial Assurance & Decommissioning Funding Plan

Column 1: Radioisotope	Column 2: Limit for F/A (millicuries*)	Column 3: Limit for DFP (millicuries*)
Calcium-45	10	1,000
Carbon-14	100	10,000
Chlorine-36	10	1,000
Hydrogen-3	1,000	100,000
Zinc-65	10	1,000

* 1 millicurie = 37 MBq

Note: 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*', contains approved wording for each mechanism authorized by the rule to guarantee or secure funds except for the Statement of Intent for government licensees.

Record Keeping

The requirements for maintaining records important to decommissioning, including the type of information required, are stated in **12 VAC 5-481-450 C 8**. All licensees are required to maintain these records in an identified location until the site is released for unrestricted use. In the event that the licensed activities are transferred to another person or entity, these records shall be transferred to the new licensee prior to transfer of the licensed activities. The new licensee is responsible for maintaining these records until the license is terminated. When the license is terminated, these records shall be transferred to VDH.

12 VAC 5-481-450 C 8 Requirements for Disposition of Records Important to Decommissioning:

- Before licensed activities are transferred or assigned according to **12 VAC 5-481-490 B**, transfer to the new licensee
- OR**
- Before the license is terminated, transfer records to VDH.

References: Can be accessed on the NRC website at www.nrc.gov.

- NRC Regulatory Guide 3.66, '*Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72*.'
- NRC Policy and Guidance Directive FC 90-2 (Revision. 1), '*Standard Review Plan for Evaluating Compliance with Decommissioning Requirements*.'

Item 9: Facilities and Equipment

Rule: 12 VAC 5-481-450 A 2, 450 A 4; 450 C; VAC 5-481-630, 720,730, 840 & 1160.

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property. They must minimize the possibility of contamination and keep exposures to workers and the public ALARA.

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

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

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

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

These records are required to be maintained in an identifiable location. Facilities are required to meet VDH criteria prior to release. Therefore, careful facility design is important to prevent contamination, or facilitate decontamination, reducing the costs needed for decommissioning. For further information, see the section titled, 'Financial Assurance and Record Keeping for Decommissioning.'

For additional guidance regarding facilities and equipment, refer to **Appendix K**.

If radioactive materials will be used with animals, include a description of the animal handling and housing facilities. (See **Appendix H**)

Response from Applicant:

<p>Item 9. FACILITIES AND EQUIPMENT (Check all that apply and attach the requested information).</p> <p><input type="checkbox"/> A description is provided of the facilities and equipment at each location where radioactive material will be used. Diagrams should be drawn to a specified scale, or dimensions should be indicated. For facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted.</p> <p>NOTE: See Appendix K of VAREG "Guidance for Academic, Research and Development and Other Licenses of Limited Scope for guidance.</p> <p style="text-align: center;">AND, IF APPLICABLE</p> <p><input type="checkbox"/> A description showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety is provided.</p> <p style="text-align: center;">AND/OR</p> <p><input type="checkbox"/> For radioactive materials that may become airborne, diagrams contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems. (Diagrams are attached)</p>
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Item 10: Radiation Safety Program

Item 10.1: Radiation Safety Audit Program

Rule: 12 VAC 5-481-630, 12 VAC 5-481-990

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

- Compliance with VDH and DOT regulations (as applicable), and the terms and conditions of the license;
- Occupational doses and doses to members of the public are ALARA (12 VAC 5-481-630); and
- Records of audits and other reviews of program content are maintained for 3 years.

Discussion: **Appendix L** contains a sample audit program that is specific to ARDL licensees and is acceptable to the agency. All areas indicated in **Appendix L** may not be applicable to every licensee and may not need to be addressed during each audit. For example, licensees do not need to address areas which do not apply to their activities, and activities which have not occurred since the last audit. The licensee shall periodically (at least annually) review the radiation protection program content and implementation.

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 radioactive material users to determine if, for example, Operating and Emergency Procedures are available and are being followed.

If an audit identifies violations of VDH requirements, the licensee should first 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'* dated May 1, 1996, provides guidance on this subject. Certain identified problems or potential violations may require notification or a report to the VDH. Licensees are encouraged to contact the agency for guidance if there is any uncertainty regarding a reporting requirement. The agency routinely reviews licensee's 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. The agency can exercise discretion and may elect not to cite the licensee for these violations if prompt and effective corrective actions are implemented.

Licensees must maintain records of these audits and other reviews of program content and implementation for 3 years from the date of the record. Records of these audits should include the following information: date of audit, name of person(s) who conducted audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up. These records must be maintained for inspections by the agency.

Response from Applicant:

Item 10.1 Radiation Safety Audit Program

The applicant is not required to submit its audit program to the agency for review during the licensing phase. This matter will be examined during an inspection.

References: NRC Information Notice 96-28, 'Suggested Guidance Relating to Development and Implementation of Corrective Action' dated May 1, 1996. Information Notice 96-28 is available on the Internet at <http://www.nrc.gov>.

Item 10.2: Radiation Monitoring Instruments

Rule: 12 VAC 5-481-450, 750 & 1000

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

Discussion: Licensees shall possess, or have access to, calibrated radiation detection/measurement instruments or licensed services to perform, as necessary the following:

- Package surveys;
- Contamination surveys;
- Sealed source leak tests;
- Air sampling measurements;
- Bioassay measurements;
- Effluent release measurements; and
- Unrestricted area dose rate measurements.

For the purposes of this document, survey instruments are defined as any device used to measure the radiological conditions at a licensed facility. Some of the survey instruments that may be used to perform the above functions include:

- Portable or stationary count rate meters;
- Portable or stationary dose rate or exposure rate meters;
- Single or Multichannel Analyzers;
- Liquid Scintillation Counters (LSC);
- Gamma Counters;
- Proportional Counters; and
- Solid State Detectors.

The choice of instrument should be appropriate for the type of radiation to be measured, and for the type of measurement to be taken (count rate, dose rate, etc.). Applications should include descriptions of the instrumentation available for use and instrumentation applicants intend to purchase prior to starting licensed activities. The description should include type of instrument and probe, and the instrument's intended purpose.

VDH requires that calibrations be performed by the instrument manufacturer or a person specifically authorized by VDH, the NRC or another Agreement State, unless the applicant specifically requests this authorization.

Applicants seeking authorization to perform survey instrument calibrations shall submit procedures for review.

Appendix M provides information about instrument specifications and calibration procedures.

Response from Applicant:

Item 10.2 Radiation Monitoring Instruments (Check one box)

We will use instruments that meet the radiation monitoring instruments specifications published in Appendix M of VAREG 'Guidance for Academic, Research and Development and Other Licenses of Limited Scope'. We reserve the right to upgrade our survey instruments as necessary.

OR

We will use instruments that meet the radiation monitoring instrument specifications published in Appendix M of VAREG "Guidance for Academic, Research and Development and Other License of Limited Scope". Additionally we will implement the model survey meter calibration program published in Appendix M of VAREG 'Guidance for Academic Research and Development and Other License of Limited Scope'. We reserve the right to upgrade our survey instruments as necessary.

OR

We will provide a description of alternative equipment and/or procedures for ensuring that appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration and calibration frequency of survey equipment will be performed. We reserve the right to upgrade our survey instruments as necessary. (Procedures are attached).

Item 10.3: Material Receipt and Accountability

Rule: 12 VAC 5-481-100; 420, 430, 450, 480 B; 570; 740 , 750, 840, 900; & 3100.

Criteria: Licensees must do the following:

- Develop, implement, and maintain written procedures for safely opening packages;
- Develop, implement, and maintain procedures to ensure security and accountability of licensed material; and
- Maintain records of receipt, transfer, and disposal of licensed material.

Discussion: Licensees are required to develop, implement, and maintain written procedures for safely opening packages in accordance with 12 VAC 5-481-900. Some packages may require special procedures that take into consideration the type, quantity, or half-life of the nuclide being delivered.

Licensees need to make arrangements to receive radioactive packages when they are delivered or to be notified when radioactive packages arrive at the carrier's terminal so that the licensee can pick up the package expeditiously. A sample procedure for safely opening packages containing licensed materials is included in **Appendix N**.

In limited scope radiation safety programs, the RSO or his/her staff usually receives the incoming package directly from the carrier, and performs all verification, surveying, opening, and documentation for inventory. The package is then delivered to the AU, or the AU retrieves the package from the RSO. If the package is transported over public roads by the licensee, it must be repackaged and transported in accordance with DOT regulations.

If the package of licensed material is delivered to the licensed facility's receiving department, individuals working in that department should be trained to do the following:

- Identify the package as radioactive by labeling and shipping papers;
- Segregate the package from other incoming items in a secured area until released by the RSO;
- Notify the RSO.

When notified that a package of licensed material has arrived, the RSO or his/her staff should retrieve the package and follow the safe opening procedures.

12 VAC 5-481-900 states the requirements for monitoring packages containing licensed material. These requirements are described in **Table 5** below.

Table 5: Package Monitoring Requirements

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

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

12 VAC 5-481-900 requires that the licensee immediately notify the final delivery carrier and, by telephone and either telegram or facsimile, VDH, when removable radioactive surface contamination or external radiation levels exceeds the limits of **49 CFR 173.443**.

Licensed materials must be tracked from "receipt to disposal" in order to ensure accountability and to ensure that possession limits listed on the license are not exceeded. Licensees must maintain records of receipt, transfer, and disposal of licensed material.

Licensees frequently possess radioactive material, which is generally licensed or distributed to them as an exempt quantity in addition to that which is specifically listed on their license. **12 VAC 5-481-420 & 430** provides information regarding generally licensed devices. Any person who acquires, receives, possesses, uses, or transfers a generally licensed device must do so in accordance with the provisions of the general license. Generally licensed material possessed by a specific licensee may continue to be possessed under a general license. A specific license does not automatically remove general licensee status nor automatically "move" generally licensed material to the specific license. The agency recognizes that multiple authorizations can create some confusion and, therefore, a specific licensee always has the option of receiving and possessing radioactive materials that "qualify" for a general license, by adding these to its specific license.

Similarly, radioactive material received by a specific licensee, that is distributed to them under an exemption from the requirements for a license, is not subject to the terms and conditions of the specific license. Any person may receive radioactive material that is exempt from the requirements of a license pursuant to **12 VAC 5-481-390 & 400** and **12 VAC 5-481-90**. Such materials may include "exempt quantities" of radioactive materials that do not exceed the applicable quantity listed in **12 VAC 5-481 3730**, as well as items such as smoke detectors and self-luminous watches, that are distributed in accordance with other VDH requirements. Most licensees do not possess or control these type of devices under the provisions of their specific license and the agency does not require or encourage this practice; however, as stated above, the specific licensee always has the option of adding these

materials to its license, and controlling them under the conditions of the specific license. In any case, licensees are required to ensure that dose limits are not exceeded, whether or not the dose results from licensed sources or unlicensed sources.

Some facilities may have separate laboratories or locations which use material for in-vitro assay that may be possessed under the general license in **12 VAC 5-481-430 G**. Each location is a separate general license from the other. The multiple locations are not considered to operate under a single general license and are not considered part of the specific license. The possession limit of 7.4 MBq (200 microcuries), only applies to a total amount of iodine-125 (I-125), iodine-131 (I-131), selenium-75 (Se-75), iron-59 (Fe-59) or cobalt-57 (Co-57) used or stored in one location.

It is recognized that loss, theft, or misplacement of licensed material can occur; however, licensees must have in place an accountability and control system for promptly detecting losses of licensed material.

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

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

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

VDH requirements applicable to transfers are stated in **12 VAC 5-481-560**. Sample policy transfer statements are included in **Appendix N**. Transfer of licensed materials within the facility may require special procedures to ensure proper control. In many facilities, pieces of laboratory equipment or components including refrigerators and freezers will become contaminated. Removal of these items for maintenance, repair, or disposal should also be carefully controlled.

Licensees must maintain records of receipt, transfer, and disposal (as waste) of all licensed material. **Table 6** below lists each type of record and how long the record must be maintained. Other records such as transfer records could be linked to radioactive material inventory records. Receipt records should also document cases where excessive radiation levels or radioactive contamination were found on packages or containers of material received and describe the action taken.

Table 6: 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

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

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

See **Item 12 ‘Waste Management’** for additional information.

Information about locations where licensed material is used or stored are among the records important to decommissioning and required by **12 VAC 5-481-450 C 8**. See the section on ‘Financial Assurance and Record Keeping for Decommissioning’ for additional information.

Response from Applicant:

Item 10.3 Material Receipt and Accountability (Check all that apply)

Unsealed Sources

We will submit procedure(s) for ensuring radioactive material accountability.

Sealed Sources

We will perform physical inventories at intervals not to exceed 6 month, to account for all sealed sources and devices received and possessed under the license.

OR

We will submit a description of the frequency and procedures for ensuring that no sealed sources have been lost, stolen or misplaced. (Description is attached).

Note: No response is needed from applicants for package opening procedures. Package opening procedures will be reviewed during VDH inspections. Alternative responses will be evaluated using the Criteria listed above.

Item 10.4: Occupational Dosimetry

Rule: 12 VAC 5-481-640, 650, 670, 700, 710, 750, 1040, 1100, & 2280

Criteria: The use of individual monitoring devices for external dose is required for:

- Adults who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
 - 5 mSv (0.5 rem) deep-dose equivalent.
 - 15 mSv (1.5 rems) eye dose equivalent.
 - 50 mSv (5 rems) shallow-dose equivalent to the skin.
 - 50 mSv (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):
 - 0.5 mSv (0.05 rem) deep-dose equivalent.
 - 1.5 mSv (0.15 rem) eye dose equivalent.
 - 5 mSv (0.5 rem) shallow-dose equivalent to the skin.
 - 5 mSv (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 mSv (100 mrem) deep-dose equivalent, although the dose limit applies to the entire gestation period; and
- Individuals entering a high or very high radiation area.

Internal exposure monitoring (not necessarily individual monitoring devices) is required for:

- Adults likely to receive in 1 year an intake in excess of 10% of the applicable ALIs for ingestion and inhalation.
- Minors likely to receive in 1 year a committed effective dose equivalent in excess of 1 mSv (100 mrem).
- Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 1 mSv (100 mrem).

Discussion: According to 12 VAC 5-481-760, if an adult (individual) is likely to receive in 1 year a dose greater than 10% of any applicable limit, monitoring for occupational exposure is required. The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose. This evaluation need not be made for every individual; evaluations can be made for employees with similar job functions or work areas. Further guidance on evaluating the need to provide monitoring is provided in NRC Regulatory Guide 8.34, *'Monitoring Criteria and Methods to Calculate Occupational Doses'*, dated July 1992.

If this prospective evaluation shows that the individual's dose is not likely to exceed 10% of any applicable regulatory limit, there are no recordkeeping or reporting requirements. For individuals who have received doses at other facilities in the current year, the previous dose need not be considered in this prospective evaluation. When determining the need for monitoring, only a dose that could be received at the facilities of the applicant or licensee performing the evaluation needs to be considered, including any recordkeeping and reporting requirements.

If an evaluation determined that monitoring was not required and a subsequent evaluation indicates that the 10% regulatory threshold may or will be exceeded, the dose received by an individual when monitoring was not provided should be estimated, recorded, and reported (if required). These estimates can be based on any combination of work location radiation monitoring, survey results, monitoring results of individuals in similar work situations, or other estimates to produce a "best estimate" of the actual dose received.

If the prospective dose evaluation shows that the individual is likely to exceed 10% of an applicable limit, monitoring is required per **12 VAC 5-481-760**. Recordkeeping of the results of monitoring performed regardless of the actual dose received is required by **12 VAC 5-481-1040**.

A common method for dose evaluation is to monitor workers' dose with whole body and extremity dosimetry (TLDs film, ring badge, etc.) provided by a National Voluntary Laboratory Accreditation Program (NVLAP)-approved dosimetry service. Workers are typically monitored for a year or more to determine actual annual dose. The monitoring results are then used to determine the need to continue monitoring workers. The dose to workers may need to be reevaluated if there are changes to the licensee's program, such as procedures, frequency of use, quantity of licensed material used, isotopes used, etc.

For guidance about methodologies for determination of internal occupational dose and summation of occupational dose, refer to NRC Regulatory Guide 8.34, '*Monitoring Criteria and Methods to Calculate Occupational Doses*' dated July 1992, and NRC Regulatory Guide 8.9, '*Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program*' dated July 1993. NRC also has additional Regulatory Guides that have been developed for specific isotopes such as H-3 and iodine. For copies of these guidance documents contact VDH or access the NRC's web site at: <http://www.nrc.gov>.

Response from Applicant:

<p>Item 10.4 Occupational Dosimetry (Check one box)</p> <p><input type="checkbox"/> We will maintain, for inspection by VDH, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in 12 VAC 5-481-640.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged at a frequency recommended by the processor. (12 VAC 5-481-750)</p>
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Item 10.5: Public Dose

Rule: 12 VAC 5-481-630, 720, & 730

Criteria: Licensees must ensure that licensed material will be used, transported, stored, and disposed of in such a way that members of the public will not receive more than 1 mSv (100 mrem) in one year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour, from licensed operations.

Discussion: "Public dose" is defined in **12 VAC 5-481-10** 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 the licensee or registrant. Public dose does not include occupational dose, or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 12 VAC 5-481-1870, or from voluntary participation in medical research programs."

Whether the dose to an individual is an occupational dose or a public dose depends on the individuals assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) the individual is in when the dose is received.

For guidance about accepted methodologies for determining dose to members of public, please refer to **Appendix O**.

Calculating the annual dose to an individual member of the public:

- 1) Identify all potential sources of external and internal exposure to members of the public.
- 2) Identify all locations of use, transport, or storage of radioactive material.
- 3) Perform surveys of all locations of use, transport or storage of radioactive material.
- 4) Identify from survey data, each location, and maximum levels of dose rates.
- 5) Calculate predicted occupancy factors at points of maximum dose rates.
- 6) Multiply the dose rates by the number of hours in a year to produce the maximum annual dose.
- 7) Multiply the maximum annual dose by the occupancy factors to get the annual dose.
- 8) Perform the above steps for all facilities.

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

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

The licensee should review these major pathways and decide which are applicable to its operations. Licensees should design a monitoring program to ensure compliance with **12 VAC 5-481-720**. The extent and frequency of monitoring will depend upon each licensee's needs. For additional guidance regarding monitoring of effluents, refer to the section titled 'Surveys.'

12 VAC 5-481-1050 requires that licensees maintain records sufficient to demonstrate compliance with the dose limits for members of the public until VDH terminates the license. Refer to **Appendix O** for additional guidance regarding compliance with the recordkeeping requirements.

Response from Applicant:

Item 10.5 Public Dose

No response is required in this license application, however the licensee's evaluation of public dose will be examined during an inspection.

Item 10.6: Operating and Emergency Procedures

Rule: 12 VAC 5-481-450 A 2; 12 VAC 5-481-630; 12 VAC 5-481-840; 870, 880, & 890; 12 VAC 5-481-1090; 12 VAC 5-481-1100 & 1110

Criteria: Licensees are required to do all of the following:

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

Discussion: Licensees are responsible for 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. Licensees should develop and maintain written

procedures to ensure safe use of licensed material, and the procedures should also include operational and administrative guidelines. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to workers or members of the public.

General Safety Procedures

The written procedures should include the following elements:

- Contamination Controls;
- Waste Disposal Practices;
- Personnel and Area Monitoring (including limits);
- Use of Protective Clothing and Equipment;
- Record Keeping Requirements;
- Reporting Requirements; and
- Responsibilities.

These procedures should include policies for:

- Frequency of personnel monitoring;
- Use of appropriate shielding; and
- Frequent change of gloves to minimize exposure to the individual and to avoid spread of contamination in the laboratory.

Applicants should also develop radioisotope-specific procedures based on the respective hazards associated with the radioisotopes. General safety guidelines are described in **Appendix P**. Applicants should use these guidelines to develop procedures for the safe use of radioisotopes.

Licensees should determine if they have areas that require posting in accordance with **12 VAC 5-481-860**, unless they meet the exemptions listed in **12 VAC 5-481-870**. Also, containers of licensed material (including radioactive waste) must be labeled in accordance with **12 VAC 5-481-880 A**, unless they meet the exemptions in **12 VAC 5-481-890**.

Security Procedures

All licensed materials that are stored in controlled or unrestricted areas must be secured from unauthorized access or removal, so that individuals who are not knowledgeable about radioactive materials can not be exposed to or contaminated by the material, and can not take the material. When any licensed materials are in use in controlled or unrestricted areas, they must be under constant surveillance so that the radiation worker can prevent others from becoming contaminated by or exposed to the material, or to prevent 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. Applicants should develop procedures that clearly state acceptable methods to secure licensed material at their facility. Particular attention may be required to security procedures at facilities which may have unusual needs due to the activities performed, such as hot cells, animal care facilities, and waste processing facilities.

Emergency Procedures

Accidents and emergencies can happen during any operation with radioisotopes, including their transportation, use, transfer, and disposal. Such incidents can result in contamination or release of material to the environment, and unintended radiation exposure to workers and members of the public. In addition, loss or theft of licensed material, sabotage, fires, floods, etc., can adversely affect the safety of personnel and members of the public. It is therefore necessary to develop written procedures to minimize, as much as possible, the impact of these incidents on personnel, members of the public, and the environment. Applicants who plan to possess quantities of material in excess of the applicable amounts listed in **12 VAC 5-481-3750 'Radiation Protection Regulations'** are also required to submit an 'Emergency Response Plan for Responding to a Release'.

Applicants should establish written procedures to handle events 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, the licensee staff should have a clear understanding of their role in an emergency with step-by-step instructions and clear direction of whom to contact.

Licensees should have readily available a sufficient number of appropriate and calibrated survey instruments. 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. **Appendix P** includes model emergency procedures. Applicants shall develop procedures incorporating the safety features included in these model procedures.

Collection of Bioassay Samples

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

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

Response from Applicant:

Item 10.6 Safe Use Of Radionuclides And Emergency Procedures (Check all that apply)

- We will develop, implement and maintain safe use of radionuclides and emergency procedures that will meet the criteria in the section titled 'Safe Use of Radionuclides and Emergency Procedures' in VAREG 'Guidance for Academic, Research and Development and Other Licenses of Limited Scope'. (Procedures are Attached)

Item 10.7: Surveys

Rule: 12 VAC 5-481-740, 750; 1000 & 1110

Criteria: Licensees are required by **12 VAC 5-481-750** to make surveys of potential radiological hazards in their workplace. VDH requires testing to determine whether there is any radioactive leakage from sealed sources. Records of surveys and leak tests results must be maintained.

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

Radiation surveys are used to detect and evaluate contamination of:

- Facilities;
- Equipment;
- Personnel (during use, transfer, or disposal of licensed material); and
- Restricted and Unrestricted Areas.

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

12 VAC 5-481-750 states that surveys are required when it is reasonable under the circumstances to evaluate a radiological hazard and when necessary for the licensee to comply with the requirements. Many different types of surveys may need to be performed due to the particular use of licensed materials. The most important are as follows:

- 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 and where operations could expose workers to the inhalation of radioactive material or where licensed material is or could be released to unrestricted areas;
- Measurements of radioactive material concentrations in water that is released to the environment or to the sanitary sewer;
- Bioassays to determine the kinds, quantities or concentration, and in some cases, the location of radioactive material in the human body. A bioassay can be made by direct measurement (in vivo counting) or by analysis and evaluation of material excreted or removed from the human body; and
- 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 (See **Appendix Q**).

Not all instruments can measure a given type of radiation. The presence of other radiation may interfere with a detector's ability to measure the radiation of interest. Correct use of radiation detection and measurements is an important aspect of any radiation safety program.

12 VAC 5-481 'Virginia Radiation Protection Regulations' 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. **Table 12 and 13 in Appendix Q** contain contamination limits that are acceptable to VDH.

Sealed Source and Plated Foil Leak Test

12 VAC 5-481-740 requires the performance of leak tests of sealed and plated foil sources (e.g., GC) at interval not to exceed six months unless otherwise approved by the NRC or another Agreement State and specified by the SSD Registration Certificate. The measurement of the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 Ci) of the radioisotope contained in the source or foil.

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

Leak tests are not required if:

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

For more information regarding leak tests, see **Appendix R**.

Response from Applicant:

<p>Item 10.7 Surveys (Check all that apply)</p> <p><input type="checkbox"/> We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q of VAREG 'Guidance for Academic, Research and Development and Other Licenses of Limited Scope'.</p> <p style="text-align: center;">IF SEALED SOURCES ARE USED</p> <p><input type="checkbox"/> Leak tests will be performed by an organization authorized by VDH, the NRC or another Agreement State to provide leak testing services to other licensees; or by using a leak test kit supplied by an organization licensed by VDH, the NRC or another Agreement State to provide leak test kits to other licensees according to kit suppliers instructions.</p> <p>List the name and license number of organization authorized to perform or analyze leak test (Specify whether VDH, NRC, or Other Agreement State):</p> <p>Organization Name _____ License Number _____</p> <p>Note: An alternate organization may be used to perform or analyze leak test, without amending the license, provided the organization is specifically authorized by VDH, NRC or an Agreement State.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will perform our own leak testing and sample analysis. We will follow the model procedures in Appendix R of VAREG 'Guidance for Academic, Research and Development and Other Licenses of Limited Scope'.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will submit alternative procedures. (Procedures are attached)</p>
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Item 10.8: Transportation

Rule: 12 VAC 5-481-2980 & 3070; 49 CFR Parts 171-178

Criteria: Applicants who will transport or ship licensed material, including radioactive waste, must develop, implement, and maintain safety programs for transport of radioactive material to ensure compliance with VDH and U.S. Department of Transportation (DOT) regulations.

Discussion: Packages shipped by ARDL licensees frequently meet the "Limited Quantity" criteria as described in 49 CFR 173.421, and therefore could be exempt from certain DOT requirements, but they may be subject to other,

less restrictive DOT requirements (e.g., **49 CFR 173.422** and **173.424**; also see **Appendix S** for more information).

If they are not exempted, however, licensed material, including radioactive waste, must be packaged and transported in accordance with VDH and the DOT requirements if the transportation involves common carriers or the use of public highways. Licensees should develop and maintain their own radiation safety procedures for transporting licensed material within their own facilities if it does not involve the use of public highways.

Licensees should consider the safety of all individuals who may handle or may come into contact with the packages containing licensed material. Therefore, the primary considerations in packaging licensed material should be to ensure that the 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 **12 VAC 5-481-3070 9** but are ALARA.

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

Licensees shipping radioactive waste for disposal must prepare appropriate documentation as specified in **12 VAC 5-481-3710 'Virginia Radiation Protection Regulations'**.

Response from Applicant:

Item 10.8 Transportation

No response is needed from applicant in this license application, transportation issues will be reviewed during inspections

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 & Training at (202) 366-4900 or by accessing their website at <http://hazmat.dot.gov/pubtrain/ramreview.pdf>.

Item 10.9: Minimization of Contamination

Rule: **12 VAC 5-481-450 A 4**

Criteria: Applicants must describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

Discussion: When designing facilities and developing procedures for their safe use, applicants should think ahead and consider how to minimize radioactive contamination during operation, decontamination and decommissioning efforts, and radioactive waste generation. When submitting new applications, applicants should consider the following:

- Implementation of and adherence to good health physics practices in operations;
- Minimization of areas, to the extent practicable, where licensed materials are used and stored;
- Maximization of the frequency of surveys, within reason, to minimize spread of contamination in the event of a spill;

- Choice of isotope to be used, whenever practical, in consideration of half-life and chemical composition;
- Appropriate filtration of effluent streams;
- Use of non-porous materials for laboratory bench tops, flooring, etc.;
- Ventilation stacks and ductwork with minimal lengths and minimal abrupt changes in direction;
- Use of appropriate plumbing materials with minimal pipe lengths and traps; and
- Minimization of the number of disposal sites (sinks) where liquid waste is disposed.

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

Response from Applicant:

Item 10.9 Minimization of Contamination

No response is required if applicant meets the criteria in the following sections: 'Unsealed and/or Sealed Sources', 'Facilities and Equipment', 'Safe use of Radioisotopes and Emergency Procedures', 'Surveys', and 'Waste Management'.

Item 10.10: Termination of Activities

Rule: 12 VAC 5-481-450; 12 VAC 5-481-500; 12 VAC 5-481-570; 12 VAC 5-481-1260

Criteria: Pursuant to the rule requirements described above, the licensee must do the following:

- Notify the agency, in writing, within 30 days of:
 - Decision to permanently discontinue all activities involving materials authorized under the license.
- 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 **12 VAC 5-481-450 C**;
- Conduct decommissioning, as required by **12 VAC 5-481-500 F - L** and **12 VAC 5-481-1160**; and
- 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).
- Before a license is terminated, send the records important to decommissioning to VDH. If licensed activities are transferred or assigned in accordance with **12 VAC 5-481-490 B**, transfer records important to decommissioning to the new licensee.

Discussion: Useful guidance and other aids related to decommissioning are:

- NRC NUREG-1727, 'NMSS Decommissioning Standard Review Plan' dated September 2000.

- NRC NUREG/BR-0241, 'NMSS Handbook for Decommissioning Fuel Cycle and Materials Licenses', dated March 1997, contain the current regulatory guidance concerning decommissioning of facilities and termination of licenses.
- Appendix B of NRC NUREG/BR-0241 contains a comprehensive list of NRC's decommissioning regulations and guidance.
- NRC NUREG-1727 contains a list of superceded guidance; however, due to ongoing revisions, applicants are encouraged to consult with VDH staff regarding updates of decommissioning guidance.
- NRC NUREG-1575, 'Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)', dated December 1997, should be reviewed by licensees who have large facilities to decommission.
- NRC NUREG-1727 includes a table (Table C2.2) of acceptable license termination screening values of common beta/gamma radionuclides for building surface contamination.
- NRC NUREG-1727 also contains methods for conducting site-specific dose assessments for facilities with contamination levels above those in the table.

Response from Applicant:

Item 10.10 Termination Of Activities

No response is required from the applicant during the application process. Refer to section titled 'Termination of Activities' in VAREG 'Guidance for Academic Research and Development and Other License of Limited Scope'.

Note: The licensee's obligations are to undertake the necessary decommissioning activities, to submit VDH Form 'Certificate of Disposition of Materials' (**Appendix B**), and to perform any other actions as summarized in the 'Criteria'.

Item 11: Waste Management

Rule: 12 VAC 5-481-100; 12 VAC 5-481-570; 1060; 12 VAC 5-481-910, thru 960

Criteria: Radioactive waste must be disposed of in accordance with regulatory requirements and license conditions. Appropriate records of waste disposal must be maintained.

Discussion: Radioactive waste is normally generated when conducting licensed activities. Such waste may include used or unused radioactive material, unusable items contaminated with radioactive material, (e.g., absorbent paper, gloves, etc). Licensees may not receive radioactive waste from other licensees for processing, storage or disposal, unless specifically authorized by VDH.

All radioactive waste must be stored in appropriate containers until its disposal and the integrity of the waste containers must be assured. Radioactive waste containers must be appropriately labeled. All radioactive waste must be secured against unauthorized access or removal. VDH requires ARDL licensees to manage radioactive waste generated at their facilities by one or more of the following methods:

- Decay-in-storage (DIS);
- Release into sanitary sewerage;
- Transfer to an authorized recipient;
- Extended interim storage;
- Disposal of waste as if it were not radioactive (specific wastes);
- Obtaining prior approval of VDH of any alternate method;
- Release in effluents to unrestricted areas, other than into sanitary sewerage; or
- Incineration.

Licensees may choose any one or more of these methods to dispose of their radioactive waste. Most ARDL facilities store or dispose of radioactive waste by a combination of the first four methods, because of the types and amounts of licensed materials used by these facilities. Applicants wanting to dispose of radioactive waste by incineration should refer to NRC Policy and Guidance Directive PG 8-10, '*Disposal of Incinerator Ash as Ordinary Waste*' dated January 1997. Applicants should note that compliance with VDH requirements does not relieve them of their responsibility to comply with any other applicable federal, state, or local regulations. Furthermore, some of the radioactive waste may also include additional hazards, (e.g., biohazard or chemical hazard). Such waste is called "mixed waste," and its storage and disposal must also comply with all other applicable federal, state, and local regulatory requirements.

Applicants should describe their program for management and disposal of radioactive waste. The program should include procedures for handling of waste, safe and secure storage, characterization, minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. **12 VAC 5-481, 'Virginia Radiation Protection Regulations'** requires that licensees maintain all appropriate records of disposal of radioactive waste. The U.S. Environmental Protection Agency (EPA) issued guidance for developing a comprehensive program to reduce hazardous waste that, in many instances, may also include radioactive waste. NRC transmitted these guidelines to licensees in NRC IN-94-23, '*Guidance to Hazardous, Radioactive, and Mixed Waste Minimization Program*' dated March 1994.

Disposal By Decay-in-storage (DIS)

The agency has concluded that materials with half-lives of less than or equal to 120 days are appropriate for DIS. 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.

Applicants should assure that adequate space and facilities are available for the storage of such waste. Licensees can minimize the need for storage space, if the waste is segregated according to physical half-life. Waste containing radioisotopes of physical half-lives within a certain range may be stored in one container and allowed to decay for at least ten half-lives of the longest-lived radioisotope in the container. Procedures for management of such waste should include methods of segregation, surveys prior to disposal, and maintenance of records of disposal. Records should include the date when the waste was put in storage for decay, date when ten half-lives of the longest-lived radioisotope have transpired, date of disposal, and results of final survey before disposal as ordinary trash. Additionally, a procedure for disposal of radioactive waste by DIS, which incorporates the above guidelines, is provided in **Appendix T**.

Release Into Sanitary Sewerage

12 VAC 5-481-930 authorizes disposal of radioactive waste by release into a public sanitary sewerage system if each of the following conditions is met:

- Material is readily soluble (or is easily dispersible biological material) in water;
- Quantity of licensed material that the licensee releases into the sewer each month averaged over the monthly volume of water released into the sewer does not exceed the concentration specified in **12 VAC 5-481-3690**,
- 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 **12 VAC 5-481-3690** cannot exceed unity; and
- Total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 185 GBq (5 Ci) of H-3, 37 GBq (1 Ci) of C-14, and 37 GBq (1 Ci) of all other radioisotopes combined.

Licensees are responsible to demonstrate that licensed materials discharged into the public sewerage system are indeed readily soluble in water. NRC IN 94-07, '*Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20*' dated January 1994, provides acceptable criteria for evaluating solubility of liquid waste. Liquid scintillation media and ash are examples of material that may or may not be "readily dispersible." Careful consideration should be given to the possibility of reconcentration of radioisotopes that are released into the sewer. NRC alerted licensees to the potentially significant problem of reconcentration of radionuclides released to sanitary sewerage systems in NRC IN 84-94, '*Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems Permitted Under 10 CFR 20.203 (now 10 CFR 20.2003)*' dated December 1984.

12 VAC 5-481-930 is not applicable for releases to a private sewerage treatment system, a septic system, or leach fields. Licensees may make releases to these systems as effluents released to unrestricted areas pursuant to **12 VAC 5-481-720**. However, if licensed material is released to a private sewage treatment system, septic system, or leach field, the sludge or other solids from these systems may become contaminated with radioactive material. Such sludges may be required to be disposed of as radioactive waste, using one of the methods described as described in this section of this VAREG.

Applicants should provide procedures that will ensure that all releases of radioactive waste into the sanitary sewerage meet the criteria stated in **12 VAC 5-481-930** and do not exceed the monthly and annual limits specified in **12 VAC 5-481 3690**. Licensees are required to maintain accurate records of all releases of licensed material into the sanitary sewerage. A program for disposal of radioactive waste via sanitary sewer is described in **Appendix T**.

Transfer to an Authorized Recipient

Licensees may transfer radioactive waste to an authorized recipient for disposal. It is the licensee's responsibility to verify that the intended recipient is authorized to receive the radioactive waste prior to making any shipment. Almost all radioactive waste generated at ARDL facilities consist of low specific activity (LSA) material. The waste must be packaged in approved containers for shipment, and each container must identify the radioisotopes and the amounts contained in the waste. Additionally, packages must comply with the requirements of the particular burial site's license and state requirements. Each shipment must comply with all applicable VDH and DOT requirements. In some cases, the waste handling contractor may provide guidance to the licensee for packaging and transportation requirements; however, the licensee is ultimately responsible for ensuring compliance with all applicable regulatory requirements.

The shipper must provide all information required in NRC's Uniform Low-Level Radioactive Waste Manifest, and transfer this recorded manifest information to the intended recipient in accordance with **12 VAC 5-481-3710 'Virginia Radiation Protection Regulations'**. Each shipment manifest must include a certification by the waste generator, as specified in Section II of the 12 VAC 5-481-3710. Each person involved in the transfer for disposal and disposal of waste, including waste generator, waste collector, waste processor, and disposal facility operator, must comply with requirements specified in Section III of the above 12 VAC 5-481-3710.

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 and members of the public. The program should include adequate safety procedures to protect workers, members of the public, and the environment.

Disposal of Specific Waste As If It Were Not Radioactive

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

- Liquid scintillation media (including vials and other items contaminated with liquid scintillation media) containing no more than 1.85 kBq (0.05 μ Ci) of H-3 or C-14 per gram of the medium; and
- Animal carcasses or animal tissue containing no more than 1.85 kBq (0.05 μ Ci) of H-3 or C-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. Applicants must maintain accurate records of these disposals.

Note: Information Notices are available at the NRC's website: <http://www.nrc.gov>

Alternate Methods

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.

Some licensees do not have an LLW disposal facility available to them and therefore must use on-site interim storage until such time that a facility becomes available. Licensees should exhaust all possible alternatives for disposal of radioactive waste and rely upon on-site extended interim storage of radioactive waste only as a last resort. The protection of workers and the public is enhanced by disposal rather than storage of waste. Licensees may also find it more economical to dispose of radioactive waste than to store it on-site because as the available capacity decreases, the cost of disposal of radioactive waste may continue to increase. Other than DIS, LLW should be stored only when disposal capacity is unavailable and for no longer than is necessary. NRC IN 90-09, '*Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees*' dated February 1990, provides guidance to licensees for requesting an amendment to authorize extended interim storage of LLW.

Response from Applicant:

Item 11 Waste Management (Check all that apply)

- We will follow the model waste procedures published in Appendix T of VAREG "Guidance for Academic Research and Development and Other Licenses of Limited Scope."

OR

- We will follow: Decay-In-Storage or Disposal of Liquids Into Sanitary Sewerage waste procedures that are published in Appendix T of VAREG 'Guidance for Academic Research and Development and Other Licenses of Limited Scope'.

OR

- We will develop, implement and maintain procedures for waste collection, storage and disposal by any of the authorized methods described in Item 11 'Waste Management' of VAREG 'Guidance for Academic Research and Development and Other Licenses of Limited Scope'. We will contact the agency for guidance to obtain approval of any method(s) of waste disposal other than those discussed in Item 11 'Waste Management' of VAREG 'Guidance for Academic Research and Development and Other Licenses of Limited Scope'. (Procedures are attached)

OR

- If access to a radioactive waste burial site is unavailable, we will request authorization for extended interim storage of waste. We will refer to NRC IN 90-09 'Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licenses', dated February 1990, for guidance and submit the required information with this applications.

IF SEALED SOURCES ARE USED

- We will return sealed sources/devices to the manufacturer, distributor or an organization licensed by VDH, the NRC or another Agreement State.

NOTE: Applicants do not need to provide information to VDH if they plan to dispose of LLW via transfer to another authorized recipient or to dispose of liquid scintillation media or animals containing low levels of H-3 or C-14 as authorized by 12 VAC 5-481-910

Item 12: License Fees

Rule: 12 VAC 5-481-490

On VDH Form 'Application for Radioactive Material License for Academic, Research and Development and other Licenses of Limited Scope' (**Appendix A**), enter the fee category and the amount of the fee enclosed with the application.

Response from Applicant:

Item 12 License Fees (Refer to 12 VAC 5-490.)	
Category:	License fee enclosed:
	<input type="checkbox"/> Yes <input type="checkbox"/> No Amount Enclosed _____

Item 13: Certification

Individuals acting in a private capacity are required to date and sign VDH form, *'Application for Radioactive Material License for Academic, Research and Development and other Licenses of Limited Scope'* (**Appendix A**). Otherwise, representatives of the corporation or legal entity filing the application should date and sign VDH Form *'Application for Radioactive Material License for Academic, Research and Development and other Licenses of Limited Scope'* (**Appendix A**).

Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. An example delegation letter is included in **Appendix C**. As discussed previously in 'Management Responsibility,' signing the application acknowledges management's commitment and responsibilities for the radiation protection program. The agency will return all unsigned applications for proper signature.

Response from Applicant:

Item 13	
I hereby certify that this application was prepared in conformance with 12 VAC 5-481 "Radiation Protection Regulations" and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.	
SIGNATURE - Applicant Or Authorized Individual	Date signed:
Print Name and Title of above signatory.	

Note: It is a violation of 12 VAC 5-481-30 'Radiation Protection Regulations', to make a willful false statement or representation on applications or correspondence. When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

Appendix A:

VDH Form

***Application for Radioactive Material License for
Academic, Research and Development and Other
Licenses of Limited Scope***



**APPLICATION FOR A RADIOACTIVE MATERIAL LICENSE
 FOR ACADEMIC, RESEARCH AND DEVELOPMENT AND OTHER LICENSES OF
 LIMITED SCOPE**

The Virginia Department of Health (VDH) is requesting disclosure of information for obtaining a radioactive material license. Failure to provide any information may result in denial or delay of a radioactive material license.

Instructions – Complete all items if this is an initial application or an application for renewal of a license. Refer to VAREG ‘Guidance for Academic, Research and Development and other Licenses of Limited Scope’. Use supplementary sheets where necessary. Retain one copy and submit original of the entire application to the Virginia Department of Health, 109 Governor Street, Room 730, Richmond, VA 23219.

APPLICATION TYPE

Item 1 Type Of Application (Check one box)

New License Renewal License Number _____

CONTACT INFORMATION

Item 2 Name And Mailing Address Of Applicant:

Item 3 Person To Contact Regarding Application:

Applicant’s Telephone Number (Include area code);

Contact’s Telephone Number (Include area code):

() - ext

() - ext

LOCATION OF RADIOACTIVE MATERIAL

Item 4 Address(es) Where Radioactive Material Will Be Used Or Possessed (Do not use Post Office Box)

Address	Telephone Number (Include area code)
---------	--------------------------------------

Address	Telephone Number (Include area code)
---------	--------------------------------------

Address	Telephone Number (Include area code)
---------	--------------------------------------

Is radioactive material used at locations for field studies or other off-site locations? Yes No

If yes, please attach an additional sheet(s) with the locations (addresses) and a list of activities to be conducted at each location.

RADIATION SAFETY OFFICER

Item 5. Radiation Safety Officer (Check all that apply)

The name of the proposed RSO who will be responsible for ensuring that the licensee’s radiation safety program is implemented in accordance with approved procedures.

Telephone (Include Area Code) () - ext

AND

We will provide information demonstrating that the proposed RSO is qualified by training and experience.

AUTHORIZED USERS AND TRAINING

Item 6 Authorized Users (Check both boxes)

We will attach a list of each proposed authorized user with the types and quantities of licensed material to be used.

AND

Information is attached demonstrating that each proposed authorized user is qualified by training and experience to use the requested licensed material.

Item 7 Training For Individuals Working In Or Frequenting Restricted Areas
(Occupationally exposed individuals and ancillary personnel) (Check box)

A description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors and the method and frequency of training is attached.

RADIOACTIVE MATERIAL

Item 8 Radioactive Material (Attach additional pages if necessary)

UNSEALED SOURCES				
Radioisotope				
Chemical/Physical Form				
Maximum Possession Limit				
Proposed Use				

SEALED SOURCES				
Radioisotope				
Chemical/Physical Form	SEALED SOURCE	SEALED SOURCE	SEALED SOURCE	SEALED SOURCE
Sealed Source Manufacturer or Distributor and Model Number				
Device Manufacturer or Distributor and Model Number				
Sealed Source Device Registration Sheet Number				
Maximum Possession Limit				
Proposed Use				

FACILITIES AND EQUIPMENT

Item 9. FACILITIES AND EQUIPMENT (Check all that apply and attach the requested information.)

- A description is provided of the facilities and equipment at each location where radioactive material will be used. Diagrams should be drawn to a specified scale, or dimensions should be indicated. For facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted.

NOTE: See Appendix K of VAREG "Guidance for Academic, Research and Development and Other Licenses of limited Scope" for guidance.

AND, IF APPLICABLE

- A description showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety is provided.

AND/OR

- For radioactive materials that may become airborne, diagrams contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems. (Diagrams are attached)
-

RADIATION SAFETY PROGRAM

Item 10.1 Radiation Safety Audit Program

The applicant is not required to submit its audit program to the agency for review during the licensing phase. This matter will be examined during an inspection.

Item 10.2 Radiation Monitoring Instruments (Check one box)

- We will use instruments that meet the radiation monitoring instruments specifications published in Appendix M of VAREG "Guidance for Academic, Research and Development and Other Licenses of Limited Scope." We reserve the right to upgrade our survey instruments as necessary.

OR

- We will use instruments that meet the radiation monitoring instrument specifications published in Appendix M of VAREG "Guidance for Academic, Research and Development and Other License of Limited Scope." Additionally we will implement the model survey meter calibration program published in Appendix M of VAREG "Guidance for Academic Research and Development and Other License of Limited Scope." We reserve the right to upgrade our survey instruments as necessary.

OR

- We will provide a description of alternative equipment and/or procedures for ensuring that appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration and calibration frequency of survey equipment will be performed. We reserve the right to upgrade our survey instruments as necessary.
-

Item 10.3 Material Receipt and Accountability (Check all that apply)

Unsealed Sources

- We will submit procedure(s) for ensuring radioactive material accountability.

Sealed Sources

- We will perform physical inventories at intervals not to exceed 6 month, to account for all sealed sources and devices received and possessed under the license.

OR

- We will submit a description of the frequency and procedures for ensuring that no gauge has been lost, stolen or misplaced.
-

Item 10.4 Occupational Dosimetry (Check one box)

- We will maintain, for inspection by VDH, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in 12 VAC 5-481-640.
- OR*
- We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged at a frequency recommended by the processor. (12 VAC 5-481-750)

Item 10.5 Public Dose

No response is required in this license application, however the licensee's evaluation of public dose will be examined during an inspection.

Item 10.6 Safe Use of Radionuclides and Emergency Procedures

- We will develop, implement and maintain safe use of radionuclides and emergency procedures that will meet the criteria in the section titled 'Safe Use of Radionuclides and Emergency Procedures' in VAREG 'Guidance for Academic, Research and Development and Other Licenses of Limited Scope'. (Procedures are attached)

Item 10.7 Surveys (Check all that apply)

- We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q of VAREG 'Guidance for Academic, Research and Development and Other Licenses of Limited Scope'.
- IF SEALED SOURCES ARE USED*
- Leak tests will be performed by an organization authorized by VDH, the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test kit supplied by an organization licensed by VDH, the NRC or an Agreement State to provide leak test kits to other licensees according to kit supplier's instructions.

List the name and license number of organization authorized to perform or analyze leak test (Specify whether VDH, NRC, or other Agreement State):

Organization Name _____ License Number _____

Note: An alternate organization may be used to perform or analyze leak test, without amending the license, provided the organization is specifically authorized by VDH, NRC or an Agreement State.

OR

- We will perform our own leak testing and sample analysis. We will follow the procedures published in Appendix R of VAREG 'Guidance for Academic, Research and Development and Other Licenses of Limited Scope'.
- OR*
- We will submit alternative procedures. (Procedures are attached)

Item 10.8 Transportation

No response is needed from applicant in this license application; transportation issues will be reviewed during inspections.

Item 10.9 Minimization of Contamination

No response is required if applicant meets the criteria in the following sections: 'Unsealed and/or Sealed Sources', 'Facilities and Equipment', 'Safe use of Radioisotopes and Emergency Procedures', 'Surveys', and 'Waste Management'

Item 10.10 Termination Of Activities

No response is required from the applicant during the application process. Refer to section titled 'Termination of Activities' in VAREG 'Guidance for Academic Research and Development and Other License of Limited Scope'.

Item 11 Waste Management (Check all that apply)

We will follow the model waste procedures published in Appendix T of VAREG "Guidance for Academic Research and Development and Other Licenses of Limited Scope."

OR

We will follow: Decay-In-Storage or Disposal of Liquids Into Sanitary Sewerage waste procedures that are published in Appendix T of VAREG 'Guidance for Academic Research and Development and Other Licenses of Limited Scope'.

OR

We will develop, implement and maintain procedures for waste collection, storage and disposal by any of the authorized methods described in Item 11 'Waste Management' of VAREG 'Guidance for Academic Research and Development and Other Licenses of Limited Scope'. We will contact VDH for guidance to obtain approval of any method(s) of waste disposal other than those discussed in Item 11 'Waste Management' of VAREG 'Guidance for Academic Research and Development and Other Licenses of Limited Scope'. (Procedures are attached)

OR

If access to a radioactive waste burial site is unavailable, we will request authorization for extended interim storage of waste. We will refer to NRC IN 90-09 'Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licenses', dated February 1990, for guidance and submit the required information with this applications.

IF SEALED SOURCES ARE USED

We will return sealed sources/devices to the manufacturer, distributor or an organization licensed by DHFS, the NRC or another Agreement State.

NOTE: Applicants do not need to provide information to VDH if they plan to dispose of LLW via transfer to another authorized recipient or to dispose of liquid scintillation media or animals containing low levels of H-3 or C-14 as authorized by 12 VAC 5-481-910.

SPECIFIC LICENSE FEE

Item 12 License Fees (Refer to 12 VAC 5-481-490.)

Category:	License fee enclosed: <input type="checkbox"/> Yes <input type="checkbox"/> No Amount Enclosed _____
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CERTIFICATION (To be signed by an individual authorized to make binding commitments on behalf of the applicant.)

Item 13

I hereby certify that this application was prepared in conformance with 12 VAC 5-481 "Virginia Radiation Protection Regulations" and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.

SIGNATURE - Applicant Or Authorized Individual	Date signed
--	-------------

Print Name and Title of above signatory

Appendix B:

VDH FORM

Certificate of Disposition of Material



CERTIFICATE OF DISPOSITION OF MATERIALS

Completion of this form is required to complete termination of a Radioactive Material License as outlined in 12 VAC 5-481-500. Failure to provide information will result in this request for termination of a specific license not being processed.

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

CONTACT INFORMATION

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

TERMINATION AND DISPOSITION INFORMATION

The following information is provided in accordance with 12 VAC 5-481-500. (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 12 VAC 5-481-1160 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 12 VAC 5-481-500 L. Specify the survey instrument(s) used and certify that each instrument is properly calibrated as required in 12 VAC 5-481-500 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:

Sample Correspondence Delegation Letter

SAMPLE CORRESPONDENCE DELEGATION LETTER

[date]

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

To <NAME>,<TITLE>:

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

As [job title] of [name of licensee], I have reviewed the application/request dated [insert date] and concur in the statements and representations contained therein.

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

Signature

Title

Date

Appendix D:
Gas Chromatography Devices

Gas Chromatography Devices

This appendix may be used as guidance to request authorization for a Gas Chromatography devices on an Academic, Research & Development License.

Note: For use of X-ray Fluorescence Analyzers (XRFs) refer to VAREG, EPI 720 -A 'Guidance for Portable Gauges or XRF Devices.

Rule

Licenses are subject to all applicable provisions of the regulations in **12 VAC 5-481, 'Radiation Protection Regulations'** as they pertain to GC's.

Information for completing **Items 1 through 4** of the application have already been provided in this VAREG.

Additional information for **Item 4** is provided below.

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

Specify the street address, city, and state or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown) for each facility at which licensed material will be used or stored. **A Post Office Box address is not acceptable.** In addition, state whether the GC will be used at temporary jobsites.

Item 5: Radiation Safety Officer

Provide the name of the person(s) who will be responsible for the GCs. That person(s) will be specifically named on the license.

If no repair or maintenance on the GC is proposed by the applicant, then no specific training and experience in the use and handling of radioactive materials is necessary for individuals who will use the device(s) or supervise its use. No special training or experience is needed to perform leak tests using a leak-test kit or to clean detector cells used in GC devices, provided the source or foil is not removed from the detector cell.

If the applicant proposes to perform any operations that involve removal of sources containing radioactive material from the device or maintenance and repair of a device that involves the source, then they must ensure a "responsible individual" performs these operations. The responsible individual shall have received instruction and training in the principles and practices of radiation safety, the use of radiation detection instruments, and the performance of these operations. Such training may normally be accomplished in 1 or 2 days. In the application, provide the following information:

- Name of each responsible individual who will perform the operations
- Outline of the instruction and training each responsible individual has received in the principles and practices of radiation safety, the use of radiation detection instruments, and the operations that will be performed, including actual practice in performing the operations. The amount of time spent on each topic in the training should be specified.

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

Persons who will only use a GC under the supervision of the responsible individual named in **Item 6** need no special training and their names do not need to be submitted. These supervised individuals should not be permitted to perform any maintenance or repair operations. Only responsible individuals specifically named in **Item 6** shall perform such operations.

Item 8: Radioactive Material

1. Provide the radioisotopes(s) that will be used in each GC.
2. Provide the manufacturer and model number of the detector cell, foil source, plated source, or sealed source that will be used in each GC.
3. Specify the quantity (activity) of radioactive material that will be in each foil source, plated source, or other sealed source. Provide the number of sources of each foil source, plated source or sealed source that will be possessed, if known. If the total number for each type of source is unknown, provide an anticipated total.

Note: GCs that contain titanium tritide foils or scandium tritide foils require operating temperature control mechanisms and venting to the outside. Provide information on operating temperature controls and venting information with the application, if these kinds of foils are requested in the application.

Purpose For Which Licensed Material Will Be Used

Specify the intended purpose for each GC to be used.

Item 9: Facilities and Equipment

12 VAC 5-481-450 A 2 states that an application will be approved if the applicant's proposed equipment and facilities are adequate to protect health and to minimize danger to life or property. **12 VAC 5-481-840 A** also states that licensed material stored in an unrestricted area must be secured from unauthorized removal, and licensed materials in an unrestricted area and not in storage must be under the constant surveillance and immediate control of the licensee.

The room, laboratory, or storage area in which the device is located should be: (1) accessible only to persons authorized to use the device and (2) locked when an authorized person is not physically present. The application should state that the laboratory or area will be locked or secured when an authorized person is not present. The room, laboratory, or storage area cannot be considered a restricted area if it is accessible to unauthorized persons.

Item 10: Radiation Safety Program

Item 10.1 Audit Program

Licensees must review the content and implementation of their radiation protection programs annually, to ensure compliance with VDH rules and with the terms and conditions of the license. **Appendix L** contains a suggested audit program that is acceptable to the agency. All areas indicated in **Appendix L** may not be applicable to every licensee and may not need to be addressed during each audit.

Item 10.2 Radiation Monitoring Instruments

A survey meter for routine uses of GCs is not required.

If maintenance and repair operations are proposed as described in **Item 7**, and the operations involve the sealed source, provide information about what surveys will be performed, what type of survey meter will be used for conducting surveys, the range of the survey instrument, and calibration information including frequency of calibration. It is not necessary to specify the manufacturer and model number of the survey meter. For more information on survey meters, see Item 10.2 'Radiation Monitoring Instruments,' in the main body of this VAREG.

Item 10.3 Material Receipt and Accountability

Licensees are required to maintain records of receipt, transfer, and disposal of licensed material. Loss, theft, or misplacement of licensed material can occur; therefore control and accountability of GCs must be ensured. Licensees who use and/or possess sealed sources are required by license conditions to perform inventories of sealed sources every six months. Some sealed sources may not be in use or are rarely used and are placed in storage. In these cases, licensees should confirm that these sealed sources have not been disturbed at least every 6 months.

Item 10.4 Occupational Dose

Personnel monitoring devices are not required for the following:

- Routine use and normal operation of GCs; and
- Maintenance and repair operations described in **Item 10.6**, if the radiation source in the GCs are in a gaseous form or is nickel-63 (Ni-63).

If proposed uses of GCs include the maintenance and repair operations described in **Item 10.6**, and these operations involve sealed sources other than in gaseous form or Ni-63, an evaluation for personnel monitoring devices is required for persons performing these operations.

The application should indicate that maintenance and/or repair personnel will be provided with either film badges, OSLs or thermoluminescence dosimeters (TLDs) for use while performing service operations or provide a dose evaluation which indicates that personnel will not be required to wear monitoring devices.

Item 10.6 Safe Use of Radionuclides and Emergency Procedures

If authorization has been requested to perform maintenance and repair operations then state in the application that the written procedures provided by the device manufacturer will be followed for each such operation requested. If a procedure will be followed other than that provided by the device manufacturer, submit a proposed procedure to use for each operation requested.

Item 10.7 Surveys (Leak Testing)

VDH requires testing to determine whether there is any radioactive leakage from sealed/plated foil sources. Records of surveys and leak tests results must be maintained.

When issued, a license will require performance of leak tests of sealed/plated foil sources at intervals as approved by the NRC or another Agreement State and as specified by the SSD Registration Certificate. The measurement of

the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 Ci) of radioactivity.

Manufacturers, consultants, and other organizations may be authorized by VDH, the NRC or another Agreement State either to perform the entire leak test sequence for other licensees or to provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample according to the sealed source or plated foil manufacturer's (distributor's) and the kit supplier's instructions and return it to the kit supplier for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. Licensees may also be authorized to conduct the entire leak test sequence themselves. For more information about leak testing sealed/plated foil sources, see 'Surveys,' in the main body of this VAREG.

Item 10.8 Transportation

If authorization has been requested in the application to use GCs at a temporary jobsite, the applicant must take into consideration DOT regulations, particularly blocking and bracing the device containing licensed material. The applicant is not required to submit transportation information with the application.

Item 10.9 Minimization of contamination

New license applicants are required by **12 VAC 5-481-450 A 4** to describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

Item 11: Waste Management

Because of the nature of the licensed material contained in GC devices, the usual disposal option is to transfer the licensed material to an authorized recipient. State in the application that disposal will be by transfer of the radioactive material to a licensee specifically authorized to possess it, or provide information for an alternate method of disposal for VDH review.

Authorized recipients are the original supplier of the device, a commercial firm licensed by VDH, the NRC or another Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material. No one else is authorized to receive licensed material.

Appendix E:
Information Needed for Transfer of Control
Application

Information Needed for Transfer of Control Application

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.

Definitions:

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

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

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

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 licensed program.

Reference: See the NRC website at: www.nrc.gov to obtain copies of NRC Information Notice 89-25, Revision 1, '*Unauthorized Transfer of Ownership or Control of Licensed Activities.*'

Appendix F:

Reserved

Appendix G:

Guidance on Decommissioning Funding Plan and Financial Assurance

Table 7 and 8 are used to determine the need for certification of financial assurance (F/A) for decommissioning or a decommissioning funding plan (DFP), as required by **12 VAC 5-481-450 C 1**. **Table 7** lists isotopes with a half-life of greater than or equal to 120 days. It is derived from the table given in 12 VAC 5-481-3750 and gives adjusted activities to assist in the determination. If the applicant proposes to use isotopes with a half-life greater than or equal to 120 days, divide the requested possession limit (in μCi) of the isotope by the value for that isotope in **Table 7**. If the material requested is in an unsealed form, use the value in the unsealed column. If the material requested is in a sealed form, use the value in the sealed column. Place the fraction in the proper column in worksheet **Table 8**. Add the fractions in the column and place the total in the row labeled total (i.e., "sum of the ratios").

Table 7: Isotopes With Half-lives Greater Than or Equal to 120 Days

Isotope	Unsealed (μCi)	Sealed (μCi)
americium-241	10	1×10^8
antimony-125	10000	1×10^{11}
barium-133	10000	1×10^{11}
cadmium-109	10000	1×10^{11}
calcium-45	10000	1×10^{11}
carbon-14	100000	1×10^{12}
Cerium-144	1000	1×10^{10}
Cesium-134	1000	1×10^{10}
Cesium-135	10000	1×10^{11}
Cesium-137	10000	1×10^{11}
Chlorine-36	10000	1×10^{11}
Cobalt-60	1000	1×10^{10}
Europium-152 (13 yr)	1000	1×10^{10}
Europium-154	1000	1×10^{10}
europium-155	10000	1×10^{11}
gadolinium-153	10000	1×10^{11}
gold-198	100000	1×10^{12}
hydrogen-3	1000000	1×10^{13}
indium-115	10000	1×10^{11}
iodine-129	100	1×10^9
iron-55	100000	1×10^{12}
krypton-85	100000	1×10^{12}
manganese-54	10000	1×10^{11}
nickel-59	100000	1×10^{12}
nickel-63	10000	1×10^{11}
niobium-93m	10000	1×10^{11}
platinum-193	100000	1×10^{12}
polonium-210	100	1×10^9
promethium-147	10000	1×10^{11}
rubidium-87	10000	1×10^{11}
ruthenium-106	1000	1×10^{10}
silver-110m	1000	1×10^{10}
strontium-90	100	1×10^9
technetium-97	100000	1×10^{12}
technetium-99	10000	1×10^{11}
thallium-204	10000	1×10^{11}

thulium-170	10000	1×10^{11}
thulium-171	10000	1×10^{11}
tungsten-181	10000	1×10^{11}
Zinc-65	10000	1×10^{11}
Zirconium-93	10000	1×10^{11}
Any alpha emitting Radionuclides not listed above with a half-life greater than or equal to 120 days.	10	1×10^8
Any radionuclide other than alpha emitting radionuclides, not listed above with a half-life greater than or equal to 120 days.	100	1×10^9

Table 8: Sample Worksheet for Determining Need for a Decommissioning Funding Plan or Financial Assurance

Isotope	Unsealed Byproduct Material Activity (μCi)	Sealed Byproduct Material Activity (μCi)
	\div Unsealed Value from Table G.1	\div Sealed Value from Table G.1
Total		
Funds required		
	If 1.0, enter \$0 If > 1.0 but < 10.0, enter \$225,000 If > 10.0, but < 100.0, enter \$1,125,000 If > 100.0, enter "DFP only"	If 1.0, enter \$0 If > 1.0, enter \$113,000

If the sum of the fractions is less than or equal to 1, the applicant does not need to submit certification of F/A or a DFP. If the sum of the fractions is greater than 1 but less than or equal to 100, the applicant will need to submit certification of F/A (in the amount shown above) or a DFP. If the sum of the fractions is greater than 100, the applicant must submit a DFP.

NRC Regulatory Guide 3.66, 'Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72' dated June 1990, provides sample documents for financial mechanisms.

Appendix H:

Considerations for Laboratory Animal and Veterinary Medical Uses

This appendix provides additional information on the use of radioactive materials in laboratory animals, in animals used for research in the environment, and by veterinarians.

I. AS LOW AS IS REASONABLY ACHIEVABLE (ALARA)

12 VAC 5-481-630 requires that licensees use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

Each individual who is authorized to use radioactive material should provide appropriate instruction to all individuals who work with or in the vicinity of radioactive material, and should ensure that the facility and equipment are adequate for safe use. Each worker should follow procedures developed to ensure safety and should promptly report incidents and potential problems to the authorized user or Radiation Safety Officer (RSO).

For example, a licensee may establish release criteria for cats treated with iodine-131 of 0.5 millirem/hour at one foot from the surface of the body closest to the thyroid. This would involve confining the cats at the veterinary facility until the dose rate falls to that level. This will ensure that persons caring for the cat after discharge will not be exposed to more than 100 millirem [see **12 VAC 5-481-720**] as long as direct contact with the cat is restricted to less than 2 hours a day.

If minor children or a pregnant woman reside(s) in a home where a cat is proposed for treatment, serious consideration should be given to confining the animal until the measurement at the thyroid is less than 2 millirem/hour. As a margin of safety, pet owners should be instructed to minimize direct contact with their cat.

II. LICENSEE'S FACILITY DESIGN

Facility design considerations for hot labs, animal confinement and waste storage areas.

- Restricted access to hot lab, waste storage, and confinement areas;
- Hot lab located near confinement area;
- Confinement area with dedicated ventilation;
- Stainless steel metabolic cages (easily decontaminated) should be used;
- Shielding will be provided as needed;
- Concrete floors, no drains, in confinement area;
- Continuous negative pressure ventilation in confinement area (for volatile Radioactive Material); and
- Evaluation of air concentration of radioactive materials in confinement area.

III. LABORATORY ANIMALS

A. Training

Before allowing an individual to care for animals used in studies with or treated with licensed material, the Radiation Safety Officer (RSO), Authorized User (AU), and/or veterinarian must ensure that the individual has sufficient training and experience to maintain doses ALARA, control contamination, handle waste appropriately, etc.

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

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

Appropriate on-the-job-training should consist of:

- Observing authorized personnel using survey equipment, using proper contamination control techniques, and proper disposal of radioactive material; and
- Using survey equipment, proper contamination control techniques, and proper disposal of radioactive material procedures under the supervision of, and in the physical presence of, an individual authorized to handle animals treated with licensed material or otherwise containing licensed material.

B. Contamination Control and Waste Handling

In order to minimize the spread of contamination, animals used in studies with or treated with licensed material should be housed in cages or stalls separate from other animals. The facilities, stalls, or cages shall be secured to prevent unauthorized access to the animals. Individuals caring for these animals should reduce the chance of personal contamination by wearing gloves, lab coat, and eye protection, as appropriate.

Special care should be observed when cleaning the cage or stall. The cage or stall, the bedding, and waste from the animal may contain radioactive material. Any radioactive material should be properly disposed of as described in **Item 11**, '*Waste Management*'.

Disposal of laboratory animals that contain radioactive material requires special procedures. Animal carcasses that contain less than 1.85 kBq/gram (0.05 microcuries/gram) of carbon-14 or hydrogen-3 may be disposed of by the same method as non-radioactive animal carcasses. Animal carcasses that contain radioactive material with a half-life of less than 120 days may be allowed to decay-in-storage in a freezer dedicated for radioactive material. Animal carcasses must be held for a minimum of 10 half-lives of the longest-lived isotope. After 10 half-lives, the animal carcasses may be disposed as non-radioactive, if radiation surveys (performed in a low background area and without any interposed shielding) of the carcasses at the end of the holding period indicate that radiation levels are indistinguishable from background (See **Item 11**, '*Waste Management*').

C. Radiation Safety Procedures for the Care and Handling of Animals Administered Radioactive Material

1. Only trained individuals shall be involved in the care and handling of animals that have been administered radioactive materials.
2. The door(s) to animal housing areas shall be locked at all times when animals are present. Only authorized personnel trained in radiation safety shall have access to these areas.
3. The door(s) to animal housing areas, and each cage containing a radioactive animal, shall be conspicuously posted with a "Caution Radioactive Material" sign.
4. Authorized personnel must record the appropriate information and sign the log near the door each time they enter or leave the animal housing area.
5. Personnel providing care to animals shall wear lab coats, disposable gloves (and boots, if appropriate), and whole body dosimeters (extremity dosimeters may also be required).

6. Disposable gloves and boots shall be removed at the entrance and placed in a radioactive waste container before leaving the housing area. Hands, feet, and clothing shall be checked for contamination at this time using a portable survey meter.
7. Animals shall be fed and watered using disposable dishes that will be placed, after use, in the radioactive waste container.
8. Animal excreta shall be collected daily, sealed in plastic bags, properly labeled, and frozen (if necessary). Excreta may not be disposed of as normal waste until the radiation levels from it have reached background.
9. Adequate precautions must be employed for the transfer of treated animals through unrestricted areas to prevent contamination of these areas by excreta.
10. In case of animal death, the carcass must be frozen and stored as radioactive waste until its radiation levels have reached background.
11. A radioactive contamination survey of the housing area shall be performed each day during which an animal is housed.
12. The animal housing area shall not be used for other purposes until surveys indicate that it is free of contamination.

D. Animals Used for Research in the Environment

Before a researcher releases an animal that has been injected with a radiopharmaceutical or has had radioactive seeds implanted, the researcher will ensure that the dose that members of the public will receive from the animal is within limits of **12 VAC 5-481-720**. **12 VAC 5-481- 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 that the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour. Further, the researcher may be required to perform an assessment of the impact the radioactive material will have on the environment (See the section titled '*Purpose(s) for Which Licensed Material Will Be Used*' in **Item 8 'Radioactive Material'**).

IV. VETERINARY MEDICAL USE

A. Training

The agency believes that to demonstrate adequate training and experience, the veterinarian should have training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- Radiation Protection Principles;
- Characteristics of Ionizing Radiation;
- Units of Radiation Dose and Quantities;
- Radiation Detection Instrumentation;
- Biological Hazards of Exposure to Radiation (appropriate to the types and forms of radioactive material to be used); and
- Hands-on Use of Radioactive Materials.

The length of the training (usually 40 hours) will depend upon the type, form, quantity and proposed use of the licensed material requested, but training shall cover the subjects stated.

B. Responsibilities of Veterinarians

The following list describes the responsibilities of veterinarians intending to use iodine-131 in felines.

- Patient selection;
- Evaluation of owner cooperation;
- Dose estimate;
- Dose administration;
- Patient confinement during therapy;
- Waste handling during confinement;
- Applying patient discharge criteria;
- Owner instruction for post-discharge care; and
- Patient follow-up.

C. Criteria for Patient Selection Prior to Radioiodine Administration for Veterinary Feline Therapy

Veterinarians should consider the following in their patient selection criteria. They should also perform and document the required counseling and consideration of extended confinement when minor children or a pregnant woman reside(s) in the home.

- Cats must be referred by a practitioner who has clinically documented hyperthyroidism in the cat.
- Cats should be in otherwise good health - no congestive heart failure, chronic renal failure, or other serious health problems.
- Cats belonging to owners who exhibit anxiety about radioactive material should not be accepted for treatment.
- Owners must agree to be separated from the cat for up to two weeks during therapy confinement.
- Owners must sign a consent form confirming that post-therapeutic procedures will be followed.
- Owners with minor children or pregnant women living in the home will be carefully evaluated before a cat is selected for treatment. If a decision is made to treat, detailed counseling will be given about avoiding contact between the treated animal and these individuals. Consideration should be given to extending the confinement of the animal until the exposure rate at the body surface closest to the thyroid is less than 2 millirem per hour. Such counseling and consideration must be documented.

D. Contamination Control and Waste Handling

See '*Contamination Control and Waste Handling*' in **Section III, B** above.

E. Release of Animals from a Licensee's Facility

Before a veterinarian releases an animal that has been injected with a radiopharmaceutical or has had radioactive seeds implanted, the veterinarian must ensure that the dose that members of the public (including the animal's caretaker) will receive from the animal is within limits of **12 VAC 5-481-720**. **12 VAC 5-481-720** 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 (0.002 rem) in any one hour. Furthermore, licensees should provide instructions to the animal's caretaker to keep doses ALARA.

F. Instructions to Animal Caretaker Upon Release

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations. The instructions should not, however, interfere with or contradict the best medical judgment of the veterinarian. The instructions should include the name of a knowledgeable person to contact and that person's telephone number, in case the caretaker has any questions. Additional instructions appropriate for each modality, as shown in examples below, may be provided.

G. Examples of Owner Information, Consent Form, and Caretaker Instructions

1. Owner Information and Consent Form

EXAMPLE OWNER INFORMATION AND CONSENT FORM

Radioactive iodine has been used to treat hyperthyroidism in people for over fifty years. The first reported use of radioactive iodine to treat hyperthyroid cats was in 1983. Radioactive iodine therapy is a safe and effective choice for treating hyperthyroidism in most cats.

The cat does not experience any adverse side effects from the radioactive iodine. Because the delivery of radiation is targeted to the overactive thyroid gland, the cat does not experience any radiation side effects at the normal therapy doses used to treat hyperthyroidism. The medicine is given as an injection, usually on the day the cat is admitted to the clinic. Following the treatment, the cat will be hospitalized for 5-14 days to allow most of the radioactive medicine to leave the thyroid gland or decay prior to discharge from the clinic. This is different from the situation in human nuclear medicine as most people treated with radioactive iodine for hyperthyroidism are discharged the same day they are treated.

You cannot visit your pet during therapy, nor can pets be removed from the ward until officially released. You cannot terminate therapy or arrange for early release once therapy has begun. Pets may not be boarded/hospitalized elsewhere until they meet the requirements for release.

After being released from therapy, your cat will still possess a very low level of radioactivity, being voided out primarily via urine and feces. You don't need to totally isolate your cat from people/pets, but you must follow safety precautions until the date listed on the next page. Due to the natural decay of radioactivity and continual loss of radioiodine through the urine and stool, your cat will contain no detectable level of radioactivity soon after that date.

During hospitalization, cats are housed in individual enclosures in an isolation room in the clinic. Bedding is changed regularly and fresh food and water are available at all times. Cats get plenty of attention while they are hospitalized. Please be sure to let us know if your cat has any special feeding requirements so that his/her stay can be made as comfortable as possible.

Within one to three months after therapy, 85-90% of hyperthyroid cats become normal (euthyroid), 5-7% will become hypothyroid (too little thyroid hormone in the blood) and may require oral thyroid hormone replacement therapy, and 5-7% remain somewhat hyperthyroid. Cats with persistent hyperthyroidism can be retreated three months after their initial therapy.

To be candidates for radioactive iodine therapy, all cats have screening laboratory work (CBC/Chem screen, diagnostic T4, and urinalysis) performed by the referring veterinarian within one month prior to the anticipated treatment date. We must have copies of this lab work before your cat comes for treatment. Cats with chronic renal (kidney) failure and/or advanced heart disease are not good candidates for radioactive iodine therapy.

Please let us know what medications your cat is receiving, as some medications may interfere with radioactive iodine therapy. If your cat is receiving oral anti-thyroid medication (such as Tapazole or Methimazole), it will need to be discontinued _____ days prior to therapy with radioactive iodine. If your cat requires other medication, we will continue to administer it during your cat's hospitalization.

Please read the radiation safety instructions and consent form. Feel free to discuss any questions or concerns. If you are unable/unwilling to comply with these precautions, you should consider surgical or medical management of your cat's condition.

EXAMPLE OWNER INFORMATION AND CONSENT FORM

(cont'd)

Your pet was treated with _____ millicuries of radioactive iodine on _____.
When released to your care, your pet had an exposure rate of _____ millirem per hour at one foot from its thyroid gland.

NO SPECIAL SAFETY PRECAUTIONS ARE NEEDED AFTER

Date: _____

The medication your cat has received is beneficial to the cat, but it is important that other persons not be unnecessarily exposed to radiation. With the release of the patient to your care, you are accepting responsibility for the radiation protection of yourself and all other persons who come into contact with your pet. Your cooperation is needed to comply with the laws of the Commonwealth of Virginia and to allow continued availability of this type of treatment. Please feel free to contact us regarding any specific problem or questions you may have regarding your pet's treatment or these radiation safety instructions.

1. Keep the cat confined to your home. Area wildlife, neighbors, their children and pets, are unaware of the radioactivity in its urine or feces.
2. Limit close contact (closer than one foot) to less than 10 minutes per day. Avoid prolonged face-to-face snuggling and face/hand contact with your cat's saliva and footpads.
3. Wash your hands thoroughly after handling your cat, its food dishes, or litter pan.
4. Do not allow your cat to sleep on your bed. Keep your cat in an unoccupied room at night.
5. Put a plastic liner in box before adding litter (if cat shreds liner, don't use it but discard box after date listed above). Keep box out of occupied areas and away from unsupervised dogs and children.
 - A. FOR PUBLIC SEWER: Add flushable litter to box, scoop soiled litter into toilet and flush. After the date listed above, discard any remaining soiled litter into the trash. Hold all soiled litter for an additional two weeks after the release date listed above, then send to a landfill.
 - B. FOR SEPTIC SYSTEM: Scoop soiled litter into a ziploc bag and seal. Place this bag into a second ziploc bag and seal. Discard into a covered trash can outside of your home. After the date listed above, discard any remaining soiled litter into the trash. Hold all soiled litter for an additional two weeks after the release date listed above, then send to a landfill.
 - C. IF YOU DO NOT USE SCOOPABLE LITTER: Change the litter at least every other day by removing it in the liner. Seal the liner and discard into a covered trash can outside of your home. After the date listed above, discard any remaining soiled litter into the trash. Hold all soiled litter for an additional two weeks after the release date listed above, then send to a landfill.

NOTE: Most landfills do not allow the disposal of low-level radioactive waste until the radioactivity has decayed to nearly background levels. Many solid waste disposal facilities have installed radiation detectors at entrance(s) to prevent the disposal of radioactive material at landfills. If the detectors indicate there is radioactive material in the waste truck, the waste disposal facility staff or a contractor must search the truck and remove the radioactive material, which is a costly and a time-consuming process. Therefore, it is important that you hold the litter for the recommended period of time in order to satisfy this requirement.

6. If your cat vomits/soils outside the litter box, use normal cleaning procedures. Seal all soiled paper cleaning materials in a ziploc bag. Place this bag into a second ziploc bag, seal and put in outside trash with soiled litter. Wash hands thoroughly.
7. Anyone pregnant or younger than 18 should not handle the soiled litter.
8. Keep your cat away from food preparation areas.

9. Instruct children to avoid the cat, and wash their hands if they touch it. Small children may not remember or understand these rules, so take extra precautions by having them wash their hands often, especially before eating.
10. If your pet must be seen by a veterinarian prior to the release date listed on this form, please inform the doctor of the type of treatment that your cat received and the date it was treated. Show this form to the doctor prior to the examination.
11. If your pet should die prior to the date listed on this form, please notify

Dr. _____ at _____
(veterinarian) (phone)

I have read this form and the information contained in it has been explained to me. I understand the radiation safety precautions that I must follow until the date listed above.

Owner's Signature _____ Date _____

Veterinarian's Signature _____ Date _____

Sample Instructions to Caretakers of Animals Administered Radiopharmaceuticals or Other Unsealed Materials

Radiopharmaceutical instructions, to the caretaker, should include the following topics:

- Maintaining distance from people;
- Minimizing time in public places (e.g., walks on public sidewalk, parks, beaches, grooming salon);
- Precautions to reduce the spread of radioactive contamination, including animal excreta (which may need to be held for decay)¹; and
- The length of time each of the precautions should be in effect.

Example Radiopharmaceutical Instructions

The animal has been treated with radioactive material (isotope) and still possesses a low level of radioactivity. The present level of radioactivity is below the regulatory agency level necessary for isolating the animal from humans. Because some radioactivity will be present for the next few days, it is necessary that the following safety precautions be exercised for the next _____ days:

1. The animal should be kept inside or in his/her cage/stall following hospital discharge.
2. The animal should not be permitted to have prolonged contact with children under the age of 18 for _____ days following hospital discharge. Close contact should be limited to less than _____ minutes per day.
3. Pregnant women should avoid ALL contact with the animal or its urine and/or feces for at least _____ days after discharge.
4. Family members should not be permitted to sleep with the animal for _____ days after discharge. They also should limit close contact with the animal (being within 1 meter or 3 feet of the animal) for the next _____ day(s) to no more than _____ minutes a day. Preferably, contact with the animal should be kept to a distance of more than 1 meter or 3 feet for this period.
5. Use plastic litter pan liners and a scoopable litter (for cats).
6. Disposable gloves should be worn whenever changing the litter box for the next _____ days after discharge.
7. Wash hands after contact with the animal or the litter.
8. Call _____ to discuss any other radiation safety concerns.

Many solid waste disposal facilities have installed radiation detectors at entrance(s) to prevent the disposal of radioactive material at landfills. If the detectors indicate that there is radioactive material in the waste truck, the waste disposal facility staff or a contractor must search the truck and remove the radioactive material, which is a costly and time-consuming process. Although it is proper to dispose of animal excreta in a landfill, caretakers should consider storing animal excreta in a remote location to allow the radioactive material to decay. If applicable, caretakers should contact the veterinarian for further information about the length of time that animal excreta should be held for decay.

Sample Instructions to Caretakers of Animals Implanted with Sealed Sources

A small radioactive source has been placed (implanted) inside the animal. The source is actually many small metallic pellets or seeds, which are each about 1/4" to 1/3" long, similar in size and shape to a grain of rice. The following precautions should be taken for ____ days, to minimize exposure to radiation to humans from the source inside the animal:

- Stay at a distance of ____ feet from ____;
- Maintain separate sleeping arrangements;
- Minimize the animal's time with children and pregnant women;
- Do not hold or cuddle pet;
- Avoid taking the animal on public transportation; and
- Examine any bandages that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.

If a seed or pellet has fallen out, do the following:

- Do not handle it with fingers. Use something like a spoon or tweezers to place it in a jar or other container that can be closed with a lid; and
- Place the container with the seed or pellet in a location away from people.

Telephone _____ at _____.

Appendix I:

Radiation Safety Officer Duties and Responsibilities

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

- Ensure that licensed material possessed by the licensee is limited to the types and quantities of radioactive material listed on the license.
- Maintain documentation that demonstrates that the dose to individual members of the public does not exceed the limit specified in **12 VAC 5-481-720**.
- Ensure security of radioactive material.
- Posting of documents as required by **12 VAC 5-481-860**.
- Ensure that licensed material is transported in accordance with applicable VDH and DOT requirements.
- Ensure that radiation exposures are "ALARA."
- Oversee all activities involving radioactive material, including monitoring and surveys of all areas in which radioactive material is used.
- Act as liaison with VDH and other regulatory authorities.
- Provide necessary information on all aspects of radiation protection to personnel at all levels of responsibility, pursuant to **12 VAC 5-481 'Radiation Protection Regulations'**.
- Oversee proper delivery, receipt, and conduct of radiation surveys for all shipments of radioactive material arriving at or leaving from the institution, as well as packaging and labeling all radioactive material leaving the institution.
- Determine the need for personnel monitoring, distribute and collect personnel radiation monitoring devices, evaluate bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching the limits, and recommend appropriate remedial action.
- Conduct training programs and otherwise instruct personnel in the proper procedures for handling radioactive material prior to use, at periodic intervals (refresher training), and as required by changes in procedures, equipment, rules, etc.
- Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and record keeping on waste storage and disposal records.
- Oversee the storage of radioactive material not in current use, including waste.
- Perform or arrange for leak tests on all sealed sources and calibration of radiation survey instruments.
- Maintain an inventory of all radioisotopes possessed under the license and limit the quantity to the amounts authorized by the license.
- Immediately terminate any unsafe condition or activity that is found to be a threat to public health and safety or property.
- Supervise decontamination and recovery operations.
- Maintain other records not specifically designated above, for example, records of receipts, transfers, and surveys as required by **12 VAC 5-481-100** and **12 VAC 5-481-1000**.
- Hold periodic meetings with, and provide reports to, licensee management.
- Ensure that all users are properly trained.
- Perform annual audits of the radiation safety program to ensure that the licensee is complying with all applicable VDH requirements and the terms and conditions of the license (e.g., leak tests, inventories, use limited to trained, approved users, etc.), the content and implementation of the radiation safety program to achieve occupational doses and doses to members of the public that are "ALARA" in accordance with **12 VAC 5-481-630** and required records are maintained.
- Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented (and maintained for at least 3 years) and provided to management for review; ensure that prompt action is taken to correct deficiencies.
- Ensure that the audit results and corrective actions are communicated to all personnel who use licensed material.

- Ensure that all incidents, accidents, and personnel exposure to radiation in excess of “ALARA” or **12 VAC 5-481-630 & 640** limits are investigated and reported to VDH and other appropriate authorities, if required, within the required time limits.
- Maintain understanding of and up-to-date copies of **12 VAC 5-481 ‘Virginia Radiation Protection Regulations’**, the license, revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to VDH during the licensing process.

Appendix J:

**Criteria for Acceptable Training for Authorized
Users and Radiation Safety Officers**

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

Frequency of Training

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

General Information

- A. Radiation safety
 - 1. radiation vs. contamination
 - 2. internal vs. external exposure
 - 3. biological effects of radiation
 - 4. ALARA concept
 - 5. use of time, distance, and shielding to minimize exposure.
- B. Regulatory requirements
 - 1. RSO
 - 2. material control and accountability
 - 3. personnel dosimetry
 - 4. radiation safety program audits
 - 5. transfer and disposal
 - 6. record keeping
 - 7. surveys
 - 8. postings
 - 9. labeling of containers
 - 10. handling and reporting of incidents or events
 - 11. licensing and inspection by VDH
 - 12. need for complete and accurate information
 - 13. employee protection
 - 14. deliberate misconduct.

Licensee-Specific Program Elements

- A. Authorized users and supervised users
- B. Ordering and receiving radioisotopes
- C. Applicable VDH requirements and license conditions
- D. Areas where radioactive material is used or stored
- E. Potential hazards associated with radioactive material in each area where the individuals will work
- F. Appropriate radiation safety procedures
- G. Licensee's in-house work rules. (For instructions on laboratory safety and uses of radioisotopes, see '*For Laboratory Safety and Use of Radioisotopes*' below.)
- H. Each individual's obligation to report unsafe conditions to the RSO
- I. Appropriate response to spills, emergencies or other unsafe conditions
- J. Worker's right to be informed of occupational radiation exposure and bioassay results, if applicable
- K. Locations where the licensee has posted or made available: notices, copies of pertinent VDH rule, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by **12 VAC 5-481-2260**.

- L. Emergency procedures:
 - 1. RSO name and telephone number
 - 2. immediate steps to prevent or control spread of contamination
 - 3. clean-up instructions, decontamination.

- M. Survey program:
 - 1. survey instrument accessibility
 - 2. who is responsible
 - 3. types, contamination and area
 - 4. frequency
 - 5. levels of contamination
 - 6. personnel, hands, shoes
 - 7. records

- N. Waste
 - 1. liquid
 - 2. solids
 - 3. sanitary sewer
 - 4. burial (transfer to low level waste repository)
 - 5. storage
 - 6. decay-in-storage
 - 7. waste storage surveys
 - 8. incineration
 - 9. records

- O. Dosimetry
 - 1. whole body
 - 2. extremities
 - 3. lost or replacement badges and dose assessment
 - 4. bioassay procedures
 - 5. records

- P. Instrumentation
 - 1. survey meters-use, calibration frequency, use of check sources
 - 2. analytical instruments-gas chromatographs, liquid scintillation counters

- Q. Procedures for receiving packages containing radioactive materials
 - 1. normal
 - 2. off-duty
 - 3. notification of user and RSO
 - 4. security
 - 5. exposure levels
 - 6. possession limit
 - 7. receipt of damaged packages

- R. Procedures for opening and examining packages
 - 1. leakage and contamination
 - 2. monitoring packages
 - 3. monitoring packing materials
 - 4. gloves

5. transferring material to users
- S. Animal experiments
1. description of facilities
 2. safety instructions, including handling of animals, waste, carcasses, and cleaning and decontamination of cages
 3. security
- T. Sealed sources
1. leak test requirements
 2. inventory requirements
 3. exempt quantities
 4. records
- U. Other topics, as applicable
- V. Question and answer period

For Laboratory Safety and Use of Radioisotopes

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

Appendix K:

Facilities and Equipment Considerations

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

- Restricted areas are defined as areas to which access is limited by the licensee to protect individuals against undue risks from exposure to radiation and radioactive materials. The application should contain detailed descriptions and diagrams of the facilities, including information about the shielding properties of the construction materials used. Scaled drawings and sketches should be submitted showing the relationship between restricted areas and unrestricted areas and the location of all pertinent safety-related equipment.
- 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 **12 VAC 5-481-3690**. Glove boxes are sealed boxes with transparent viewing windows, seal-able ports or doors for transferring materials and equipment, and gloves sealed to the box through which licensed materials are handled. Glove boxes are used for the containment during storage and use of liquids and solids that can become airborne particulates or aerosols. Glove boxes can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.

- Sink faucets should be designed, where possible, for operation by foot, knee, or elbow rather than by hand.
- Plumbing and ductwork should be designed to avoid radioactive contamination build-up. This build-up of contamination can create external radiation exposure hazards and problems for decommissioning.
- Shielding consisting of lead or other high-density material in the form of bricks, panels, L-shields, storage containers, or other shapes may be used on bench tops, in fume hoods or in glove boxes to reduce radiation exposure from gamma-emitting radioactive materials. Similarly, shielding of low atomic number material, such as high-density plastic, may be used to reduce the exposure from high-energy beta-emitting materials. Shielded shipping containers are frequently used for continued storage after receipt of materials.
- A particular sink should be designated for disposal of liquid radioactive waste to the sanitary sewerage system. In some cases, depending on number of users and distance between areas of use, more than one sink may need to be designated.
- Labeled waste containers should be used. These containers may be shielded as necessary, placed near the waste generating areas and away from areas frequently occupied by personnel. Additionally, these containers should be effectively enclosed to prevent airborne contamination from radioactive materials deposited.
- Remote handling tools, such as forceps or extension handles, should be used to provide distance in the handling of radioactive materials (ALARA). In addition, shielded handling devices, such as shielded

syringes, can be used to protect workers from materials that cannot be handled remotely. Pipetting should be done using appropriate devices. Pipetting by mouth should be strictly forbidden.

- Where appropriate, ventilation systems should be designed such that, in the event of an accident, they can be shut down to prevent the spread of radioactivity.
- Designated areas should be provided for coats and personal belongings, to avoid contamination.
- Areas with background radiation levels should be designated for personnel dosimetry storage when not in use.
- Areas of use should be well lighted to avoid spills and other accidents that could result in contamination build-up.
- Observation of activities conducted behind shielding with remote tools (or with extended arms and hands, within limits consistent with permissible occupational exposures) can be accomplished by mirrors, through shielded (e.g., leaded glass) windows, through transparent plastic beta shields, or by remote video monitoring.
- The combination of containment, shielding, and handling devices proposed for any use of radioactive materials should be appropriate to the type and quantity of materials to be used and to the type and duration of operations to be conducted.
- If respiratory protective equipment will be used to limit inhalation of airborne licensed material, follow the provisions of **12 VAC 5-481-830**.
- If compaction of waste is performed, ensure that facilities are adequate for the ventilation of the area where the waste is compacted. In addition, also ensure that air sampling for internal exposures is available, if needed per **12 VAC 5-481-670**.

Appendix L:

Sample Audit Program

An audit is conducted, in part, to fulfill the requirements of **12 VAC 5-481-630** for an annual review of the content and implementation of the licensee's radiation protection program. It should also identify program weaknesses and allow licensees to take early corrective actions (before a VDH inspection). During an audit, the auditor needs to keep in mind not only the requirements of VDH but also the licensee's commitments in its applications and other correspondence with VDH. 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.

The form in this appendix can be used to document the annual audit of the radiation protection program. Guidance follows on completing each section of the form. In the "remarks" portions of the form, note any deficiencies that were identified and the corrective actions taken (or to be taken).

Section 1: Audit History. Enter the date of the last audit, whether any deficiencies were identified, and whether actions were taken to correct the deficiencies.

Section 2: Organization and Scope of Program. Give a brief description of the organizational structure, noting any changes in personnel. Describe the scope of licensed activities at the audited location. Check whether the Radiation Safety Officer (RSO) is the person identified in the license and fulfills the duties specified in the license.

Section 3: Training, Retraining, and Instructions to Workers. Ensure that workers have received the training required by **12 VAC 5-481-2270**. Be sure that, before being permitted to use radioactive material, the user has received training and has a copy of the licensee's safe use and emergency procedures. Note whether refresher training is conducted in accordance with licensee commitments. Ensure that each worker has a copy of the licensee's procedures, and by interview and/or observation of selected workers that he/she can implement them.

Section 4: Audits. Verify that audits fulfill the requirements of **12 VAC 5-481-630**, are conducted in accordance with licensee commitments, and are properly documented.

Section 5: Facilities. Verify that the licensee's facilities are as described in its license documents.

Section 6: Materials. Verify that the license authorizes the quantities and types of radioactive material that the licensee possesses.

Section 7: Leak Tests. Verify that all sealed/plated foil sources are tested for leakage at the prescribed frequency in accordance with **12 VAC 5-481-740**. Records of results should be maintained.

Section 8: Inventories. Verify that inventories are conducted at least once every 6 months to account for all sources; inventory records should be maintained.

Section 9: Radiation Surveys. Verify that the licensee has appropriate, operable and calibrated survey instruments available, that the instruments are calibrated (at the required frequency) in accordance with license conditions and in accordance with **12 VAC 5-481-750**. Calibration records must be retained for 3 years after the record is made. Check that radiation levels in areas adjacent to use are within regulatory limits and in accordance with **12 VAC 5-481-750**. Verify compliance with **12 VAC 5-481-720**. Records of surveys must be retained for 3 years after the record is made.

Section 10: Receipt and Transfer of Radioactive Material (Includes Waste Disposal). Verify that packages containing radioactive material, received from others, are received, opened, and surveyed in accordance with **12 VAC 5-481-900**. Ensure that transfers are performed in accordance with **12 VAC 5-481-560**. Records of surveys, receipt, and transfer must be maintained in accordance with **12 VAC 5-481-100 & 570**.

Section 11: Transportation. Determine compliance with United States Department of Transportation (DOT) requirements. Verify that radioactive packages are prepared, marked, and labeled in accordance with **12 VAC 5-481 'Virginia Radiation Protection Regulations', Part XIII 'Transportation of Radioactive Material'** requirements. Verify that shipping papers are prepared, that they contain all needed information, and that they are readily accessible during transport.

Section 12: Personnel Radiation Protection. Evaluate the licensee's determination that unmonitored personnel are not likely to receive more than 10 percent of the allowable limits. If personnel dosimetry is provided or required, verify that it complies with **12 VAC 5-481-760** and licensee commitments. Review personnel monitoring records; compare exposures of individuals doing similar work; determine reasons for significant differences in exposures. If any worker declared her pregnancy in writing, evaluate the licensee's compliance with **12 VAC 5-481-710**. Check whether records are maintained as required by **12 VAC 5-481-1040**.

Section 13: Auditor's Independent Measurements (If Made). The auditor should make independent survey measurements and compare the results with those made or used by the licensee.

Section 14: Notification and Reports. Check on the licensee's compliance with the notification and reporting requirements in **12 VAC 5-481-1090, 1100, & 1150** and **12 VAC 5-481-1110**. Ensure that the licensee is aware of VDH telephone numbers: during normal business hours (7:30 a.m. until 4:30 p.m.) at (804) 864-8150, and after business hours to the State Emergency Operations Center (804) 674-2400 or (800) 468-8992.

Section 15: Posting and Labeling. Check for compliance with the posting and labeling requirements of **12 VAC 5-481-860** and **12 VAC 5-481-880**.

Section 16: Recordkeeping for Decommissioning. Check to determine compliance with **12 VAC 5-481-450 C**.

Section 17: Information Notices. Check to determine if the licensee is receiving information notices from VDH. Check whether the licensee took appropriate action in response to VDH mailings.

Section 18: Special License Conditions or Issues. Verify compliance with any special conditions on the license. If the licensee has any unusual aspect of its work, review and evaluate compliance with regulatory requirements.

Section 19: Continuation of Report Items. This section is self-explanatory.

Section 20: Problems or Deficiencies Noted; Recommendations. This section is self-explanatory.

Section 21: Evaluation of Other Factors. Evaluate licensee management's involvement with the radiation safety program, whether the RSO has sufficient time to perform his/her duties, and whether the licensee has sufficient staff to handle the workload and maintain compliance with regulatory requirements.

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit.

Sample Checklist

Audit Report No.: _____

License No.: _____

Date of this Audit: _____

Licensee's name and mailing address:

Audit of activities at (Address):

Contact at Audit Location: _____

Telephone No.: _____

Summary of Findings and Action:

No deficiencies

Deficiencies

Action on previous deficiencies

Recommendations:

Auditor: _____

(Signature)

Date: _____

1. AUDIT HISTORY

N/A (N/A means "Not applicable" - Initial Audit)

A. Last audit of this location conducted _____

B. Problems/deficiencies identified during last two audits or two years, whichever is longer YES NO

C. Open problems/deficiencies from previous audits:

Status Requirement	Prob./Def.	Corrective Action Taken (Y/N)	Open/Closed

D. Any previous problem/deficiency not corrected or repeated

YES NO N/A

Explain:

2. ORGANIZATION AND SCOPE OF PROGRAM

A. Briefly describe organizational structure:

1. Structure is as described in license documents

YES NO

2. Multiple authorized locations of use

YES NO

3. Briefly describe scope of activities involving radioactive material, frequency of use, staff size, etc

B. Radiation Safety Officer

1. Authorized on license

YES NO

2. Fulfills duties as RSO

YES NO

C. Use only by authorized individuals

YES NO

Remarks:

3. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

A. Instructions to workers per 12 VAC 5-481-2270.

YES NO

B. Training program required

YES NO

C. Training records maintained

YES NO

D. Evaluation of individuals' understanding of procedures and rules based on interviews, observation of selected workers

YES NO

1. Each has an up-to-date copy of the licensee's safe use and emergency procedures

YES NO

2. Adequate understanding of:

a. Current safe use procedures

YES NO

b. Emergency procedures

YES NO

E. Workers cognizant of requirements for:

1. Radiation Safety Program (12 VAC 5-481-630).

YES NO

2. Annual dose limits (12 VAC 5-481-640).

YES NO

3. VDH forms: "Cumulative Occupational Exposure History" and "Occupational Exposure Record for a Monitoring Period"

YES NO

4. 10% monitoring threshold (12 VAC 5-481-760).

YES NO

5. Dose limits to embryo/fetus and declared pregnant women (12 VAC 5-481-710).

YES NO

6. Procedures for opening packages (12 VAC 5-481-900).

YES NO

Remarks:

4. INTERNAL AUDITS, REVIEWS OR INSPECTIONS

A. Audits are conducted

YES NO

1. Audits conducted by _____

2. Frequency _____

B. Content and implementation of the radiation protection program reviewed annually (12 VAC 5-481-630).

YES NO

C. Records maintained per 12 VAC 5-481-990.

YES NO

5. FACILITIES

- A. Facilities as described in license application
Remarks:

[] YES [] NO

6. MATERIALS

- A. Isotopes, quantities, and use as authorized on license
Remarks:

[] YES [] NO

7. LEAK TESTS

- A. Leak test performed as described in correspondence with VDH (consultant; leak test kit; licensee performed)
B. Frequency: every 6 months or other interval, as approved by the NRC or another Agreement State
C. Records with appropriate information maintained
Remarks:

[] YES [] NO

[] YES [] NO

[] YES [] NO

8. INVENTORIES

- A. Conducted at 6-month intervals
B. Records with appropriate information maintained
Remarks:

[] YES [] NO

[] YES [] NO

9. RADIATION SURVEYS

- A. Instruments and Equipment:
1. Appropriate operable survey instrumentation possessed or readily available
2. Calibrated as required 12 VAC 5-481-750.
3. Calibration records maintained 12 VAC 5-481-1000
B. Briefly describe survey requirements (12 VAC 5-481-750).

[] YES [] NO

[] YES [] NO

[] YES [] NO

- C. Performed as required (12 VAC 5-481-750).

- 1. Radiation levels within regulatory limits
2. Corrective action taken and documented

[] YES [] NO

[] YES [] NO

- D. Records maintained (12 VAC 5-481-1000).

[] YES [] NO

- E. Protection of members of the public

- 1. Adequate surveys made to demonstrate either (a) that the TEDE to the individual likely to receive the highest dose does not exceed 100 mrem in a year, or (b) that if an individual were continuously present in an unrestricted area, the external dose would not exceed 2 mrem in any hour and 100 mrem in a year (12 VAC 5-481-720)..

[] YES [] NO

- 2. Unrestricted area radiation levels do not exceed 2 mrem in any one hour (12 VAC 5-481-720).

[] YES [] NO

[] YES [] NO

- 3. Records maintained (12 VAC 5-481-1000).

Remarks:

10. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL (INCLUDES WASTE DISPOSAL)

- A. Procedures describe how packages are received and by whom.
B. Written package opening procedures established and followed (12 VAC 5-481-900).
C. If package shows evidence of degradation, monitor for contamination and radiation levels
D. Monitoring of degraded packages performed within time specified (12 VAC 5-481-900).
E. Transfer(s) between licensees (including "disposal") performed per 12 VAC 5-481-560.
F. Records of receipt/transfer maintained (12 VAC 5-481-100 & 570).
G. Transfers within licensee's authorized users or locations performed as required

[] YES [] NO

[L/C]

- H. Package receipt/distribution activities evaluated for compliance with 12 VAC 5-481-900.

[] YES [] NO

Remarks:

11. TRANSPORTATION (12 VAC 5-481, Part XIII)

N/A

A. Licensee shipments are:

- 1. delivered to common carriers
- 2. transported in licensee's own private vehicle
- 3. no shipments since last audit

YES NO N/A
 YES NO N/A
 YES NO N/A
 N/A

B. Packages

- 1. Authorized packages used [49 CFR 173.415 & 173.416(b)]
- 2. Closed and sealed during transport [49 CFR 173.475(f)]

YES NO
 YES NO

C. Shipping Papers

- 1. Prepared and used [49 CFR 172.200(a)]
- 2. Proper {Shipping name, Hazard Class, UN Number, Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, Category of label, T1, Shipper's Name, Certification and Signature, Emergency Response Phone Number, "Cargo Aircraft Only" (if applicable)} [49 CFR 172.200-204]
- 3. Readily accessible during transport [49 CFR 177.718(e)]

N/A
 YES NO
 YES NO
 YES NO
 YES NO

D. Vehicles

- 1. Cargo blocked and braced [49 CFR 177.842(d)]
- 2. Placarded, if needed [49 CFR 172.504]
- 3. Proper overpacks, if used (shipping name, UN Number, labeled, statement indicating that inner package complies with specification package) [49 CFR 173.25]

YES NO
 YES NO
 YES NO

E. Any incidents reported to DOT [49 CFR 171.15 & 171.16]

YES NO

Remarks:

12. PERSONNEL RADIATION PROTECTION

A. ALARA considerations are incorporated into the Radiation Protection Program (12 VAC 5-481-630).

YES NO

B. Adequate documentation of determination that unmonitored occupationally individuals are not likely to receive >10% of allowable limit (12 VAC 5-481-640).

YES NO N/A

OR

C. External dosimetry provided and required

YES NO N/A

- 1. Supplier _____ Frequency _____
- 2. Supplier is NVLAP-approved (12 VAC 5-481-750).
- 3. Dosimeters exchanged at required frequency [L/C]

D. Occupational intake monitored and assessed (12 VAC 5-481-760).

YES NO N/A
 N/A

E. Reports

- 1. Reviewed by _____ Frequency _____
- 2. Auditor reviewed personnel monitoring records for period _____ to _____
- 3. Prior dose determined for individuals likely to receive doses (12 VAC 5-481-680).
- 4. Maximum exposures TEDE Other _____
- 5. VDH Forms or equivalent (12 VAC 5-481-1080).
 - a. "Cumulative Occupational Exposure History" forms are maintained
 - b. "Occupational Exposure Record for a Monitoring Period" forms are maintained
- 6. Worker declared her pregnancy in writing during inspection period (review records) If yes, determine compliance with 12 VAC 5-481-710. Check for records per 12 VAC 5-481-1040.

YES NO
 YES NO
 YES NO
 YES NO N/A
 YES NO N/A
 YES NO N/A

F. Records of exposures, surveys, monitoring, and evaluations maintained per 12 VAC 5-481-980, 1000, & 1080..

YES NO

Remarks:

13. AUDITOR'S INDEPENDENT MEASUREMENTS (IF MADE)

A. Survey instrument: _____ Serial No.: _____

Last calibration: _____

B. Auditor's measurements compared to licensee's

YES NO

14. NOTIFICATION AND REPORTS

- A. Licensee in compliance with 12 VAC 5-481-2280. (reports to individuals, public and occupational, monitored to show compliance)
- B. Licensee in compliance with 12 VAC 5-481-1090. (theft or loss)
- C. Licensee in compliance with 12 VAC 5-481-1100 & 12 VAC 5-481-1110 (incidents)
- D. Licensee in compliance with 12 VAC 5-481-1110.(overexposures and high radiation levels)
- E. Licensee aware of telephone number for VDH: (804) 864-8150 from 7:45 a.m. - 4:30 p.m. and (804) 674-2400 or (800) 468-8992 for after hour radiological emergencies.

N/A

YES NO

15. POSTING AND LABELING

- A. "Notice to Employees" is posted per 12 VAC 5-481-2260 C.
- B. 12 VAC 5-481 'Virginia Radiation Protection Regulations', Part IV and X, License and Operating Procedures are posted, or a notice indicating where documents can be examined is posted per 12 VAC 5-481-2260 A & B.
- C. Emergency procedures are posted per 12 VAC 5-481-2260 A 3.
- D. Other posting and labeling per 12 VAC 5-481-860 & 880.

YES NO

YES NO

YES NO

YES NO

Remarks:

16. RECORD KEEPING FOR DECOMMISSIONING (if needed)

- A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination per 12 VAC 5-481-450 C.
- B. Records include all information outlined in 12 VAC 5-481-450 C 8.

N/A

YES NO

YES NO

Remarks:

17. INFORMATION NOTICES

- A. Receipt of VDH Information Notices
- B. Appropriate action taken in response to VDH Information Notices

YES NO

YES NO

Remarks:

18. SPECIAL LICENSE CONDITIONS OR ISSUES

- A. Review special license conditions or other issues, and describe findings:

- B. Problems/deficiencies identified at licensee facilities other than at audit location:

- C. Evaluation of compliance:

N/A

19. CONTINUATION OF REPORT ITEMS

(If more space is needed, use separate sheets and attach to report.)

N/A

20. PROBLEMS OR DEFICIENCIES NOTED; RECOMMENDATIONS

Note: Briefly state (1) the requirement and (2) how and when violated. Provide recommendations for improvement.

N/A

21. EVALUATION OF OTHER FACTORS

- A. Senior licensee management is appropriately involved with the radiation safety program and/or Radiation Safety Officer (RSO) oversight
- B. RSO has sufficient time to perform his/her radiation safety duties and is not too busy with other assignments
- C. Licensee has sufficient staff

YES NO

YES NO

YES NO

Remarks/recommendations:

Appendix M:

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

Radiation Monitoring Instrument Specifications

The specifications in **Table 9** will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facilities.

Table 9: Typical Survey Instruments¹ (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; and
- Biological effects of radiation.

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

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

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

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

Procedure for Calibrating Survey Instruments

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

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

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

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

Surface Contamination Measurement Instruments

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

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

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

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

Calibration

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

Calibration Records

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

The description of the calibration should include:

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

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

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

Air Sampler Calibration

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

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

Frequency of Calibration

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

Error Limit For Measurement of Air Sample Volume

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

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

- E_C : The error in determining the calibration factor. (An acceptable estimate is the percentage error associated with the standard instrument used in the calibration.)
- E_S : Intrinsic error in reading the meter scale. (An acceptable estimate is the percentage equivalent of one-half of the smallest scale division, compared to the scale reading.)
- E_t : The percentage error in measurement of sampling time that should be kept within 1%.
- E_V : The most probable value of the cumulative percentage error in the determination of the total air volume sampled.
- E_V : can be calculated from the following equation, provided there are no additional significant sources of errors:

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

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

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

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

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

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

- Where V_s = volume at standard conditions (760 mm & 0^o C)
- V_1 = volume measured at conditions P_1 and T_1
- T_1 = temperature of V_1 in ^oK
- 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:

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

Appendix N:

Material Receipt and Accountability

Sample Procedure for Ordering and Receiving Radioactive Material

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

Sample Memorandum

Memorandum for Security Personnel

From: RSO, President, Vice President, etc.

Subject: Procedures for Receipt of Packages Containing Radioactive Material

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

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

Radiation Safety Officer (RSO): _____

Office Phone: _____

Home Phone: _____

Sample Instructions to Personnel Involved in Material Receipt

Shipping and Receiving Personnel

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

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

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

Name _____

Phone _____

For additional information on worker training, see Item 7 ' <i>Training for Individuals Working In or Frequenting Restricted Areas.</i> '
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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 **Table 5**;
- Open the outer package (following supplier's directions if provided) and remove packing slip. Open inner package to verify contents (compare requisition, packing slip and label on the bottle or other container). Check integrity of the final source container (e.g., inspecting for breakage of seals or vials, loss of liquid, discoloration of packaging material, high count rate on smear). Again check that the shipment does not exceed license possession limits. If you find anything other than expected, stop and notify the RSO;
- Survey the packing material and packages for contamination before discarding. If contamination is found, treat as radioactive waste. If no contamination is found, obliterate the radiation labels prior to discarding in the regular trash;
- Maintain records of receipt, package survey, and wipe test results; and
- Notify the final carrier, and by telephone or facsimile, VDH when removable radioactive surface contamination exceeds the limits of **49 CFR 173.44**; or external radiation levels exceed the limits of **12 VAC 5-481-3070**.

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 VDH, DOT, or U.S. Postal Service rules and 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. In any case, the RSO should approve the gift prior to the transfer.

Appendix O:

Public Dose

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

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 millisievert (mSv) [100 millirem (mrem)] in one calendar year resulting from the licensee's possession and/or use of licensed materials.
- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.

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

<p>INCLUDES doses from:</p> <ul style="list-style-type: none"> • 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 	<p>DOES NOT INCLUDE doses from:</p> <ul style="list-style-type: none"> • Sanitary sewerage discharges from licensees • Natural background radiation • Medical administration of radioactive material • Voluntary participation in medical research
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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 **12 VAC 5-481-3690**, and if an individual were continuously present in an unrestricted area the dose from external sources would not exceed 0.02 mSv (2 mrem) in an hour and 0.5 mSv (0.05 rem) in a year; and
- Demonstrating that air emissions of radioactive materials do not result in doses greater than the constraint limit of 0.1mSv (10 mrem) TEDE.

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

Measurements

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

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

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

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

Calculation Method

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

The public dose limit applies to the individual who is likely to receive the highest dose from licensed operations. Therefore, the dose calculations must consider the location with the potential for the highest internal and external exposures. A conservative calculation should assume that the individual was continuously present 24 hours a day, 365 days a year, or an occupancy factor of 1 (see **Table 10**). If the result of the calculation using an occupancy factor of 1 demonstrates that the public dose limit is not exceeded, then there is no need for further evaluation.

If the calculation demonstrates that the public dose limit is exceeded with an occupancy factor of 1, then more realistic assumptions of the individual's occupancy at the points of highest internal and external exposures may be made. The licensee may use the occupancy factors in **Table 10** or may calculate a specific occupancy factor by determining the likely fraction of time that the individual is present.

Table 10: Standard Occupancy Factors

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

Records

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

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

Appendix P:

General Topics for Safe Use of Radioisotopes and Model 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; and
- Secure all licensed material when it is not under the constant surveillance and immediate control of the user(s).

Storage of Food and Drink. Food or drink shall not be stored in refrigerators with radioisotopes.

Radionuclides-specific Procedures

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

Example 1:

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

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

Example 2:

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

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

Model Procedures for Handling Emergencies

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

General Safety Procedures to Handle Spills

- Name and telephone number of RSO or an alternate person(s) should be posted conspicuously in areas of use, so that it is readily available to workers in case of emergencies. Licensee should have emergency equipment readily available for handling spills. Spill kits should include the following:
 - Disposable gloves;
 - Housekeeping gloves;
 - Disposable lab coats;
 - Disposable head coverings;
 - Disposable shoe covers;
 - Roll of absorbent paper with plastic backing;
 - Masking tape;
 - Plastic trash bags with twist ties;
 - "Radioactive Material" labeling tape;
 - Marking pen;
 - Pre-strung "Radioactive Material" labeling tags;
 - Box of Wipes;
 - Instructions for "Emergency Procedures";
 - Clipboard with a copy of the Radioactive Spill Report Form for the facility;
 - Pencil; and
 - Appropriate survey instruments including batteries (for survey meters).

Minor Spills of Liquids and Solids

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

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

Major Spills of Liquids and Solids

- Instructions to Workers
 - Clear the area. If appropriate, survey all persons not involved in the spill and vacate the room;
 - Prevent the spread of contamination by covering the spill with absorbent paper (paper should be dampened if solids are spilled), but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated;
 - Shield the source only if it can be done without further contamination or significant increase in radiation exposure;
 - Close the room and lock or otherwise secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred;
 - Notify the RSO immediately;
 - Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with a mild soap;
 - Allow no one to return to work in the area unless approved by the RSO;
 - Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples); and
 - Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).
- Reminders to RSO
 - Confirm decontamination of personnel. If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration;
 - Supervise decontamination activities and document the results. Documentation should include location of surveys and decontamination results;
 - Determine cause and needed corrective actions; consider need for bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin; and
 - If necessary, notify VDH.

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

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

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

Minor Fires

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

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

Fires, Explosions, or Major Emergencies

- Instructions to Workers
 - Notify all persons in the area to leave immediately;
 - Notify the fire department;
 - Notify the RSO and other facility safety personnel;
 - Upon arrival of firefighters, inform them where radioactive materials are stored or where radioisotopes were being used; inform them of the present location of the licensed material and the best possible entrance route to the radiation area, as well as any precautions to avoid exposure or risk of creating radioactive contamination by use of high pressure water, etc;
 - Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples);
 - Allow no one to return to work in the area unless approved by the RSO; and
 - Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

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

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

Appendix Q:

Radiation Safety Survey Topics

Radiation Safety Survey Topics

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

Training

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

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

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

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

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

Facilities and Equipment

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

Ambient Radiation Level Surveys

- Dose-rate surveys, at a minimum, should be performed in locations where workers are exposed to radiation levels that might result in radiation doses in excess of 10% of the occupational dose limits or where an individual is working in a dose rate of 0.025 mSv (2.5 mrem/hr) or more (50 mSv/year divided by 2,000 hr/year).
- **12 VAC 5-481-720** requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year and the dose in any unrestricted area from external sources does not exceed 0.02 mSv (2 mrem) in any one hour.

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

Contamination Surveys

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

Contamination surveys should be performed:

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

Contamination Survey Frequency

Personnel should survey for contamination in locations where individuals are working with an unsealed form of radioactive material. These surveys should be done at a frequency appropriate to the types and quantities of radioactive materials in use. If the activity used is greater than or equal to the smallest annual limit on intake (ALI) (for either inhalation or ingestion) as identified in **12 VAC 5-481-3690**, then documented surveys should be performed at least daily in accordance with **12 VAC 5-481-750**.

Table 11 contains suggested contamination survey frequencies based on ALIs. The suggested frequency of surveys is based upon the amount of licensed material "in use" at any one time at any particular location. If licensed material has not been used for a period of time greater than the required survey frequency, then it is considered to be "not in use."

Table 11: Suggested Contamination Survey Frequency

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

Contamination in Unrestricted Areas

Contamination found in unrestricted areas should be immediately decontaminated to background levels. When it is not possible to get to background levels, the licensee must ensure that the amounts do not exceed the contamination levels listed in **Table 12**

Table 12: Acceptable Surface Contamination Levels for Equipment

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

^a Where surface contamination by both alpha- and beta-gamma-emitting nuclides exists, the limits established for alpha- and beta-gamma-emitting nuclides should apply independently.

^b As used in this table, dpm (disintegration per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

^c Measurements of average contaminant should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.

^d The maximum contamination level applies to an area of not more than 100 cm².

^e The amount of removable radioactive material per 100 cm² of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

* 1 Bq = 1 Disintegration per second

When equipment or facilities that are potentially contaminated are to be released for unrestricted use, **Table 12** provides the maximum acceptable residual levels for equipment and **Table 13** provides screening values for building surface contamination. 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 cm² is acceptable to indicate levels of removable contamination.

Table 13: Screening Values for Building Surface Contamination¹

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

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

Table 13 does not include screening values for radionuclides that emit alpha particles or for soil contamination. For such sites, licensees are encouraged to use, in the interim period, site-specific dose assessment based on actual site physical and environmental conditions.

Units are disintegrations per minute per 100 square centimeters (dpm/100 cm²). 1 dpm is equivalent to 0.0167 becquerel (Bq). The screening values represent surface concentrations of individual radionuclides that would be deemed in compliance with the 0.25 mSv/yr (25 mrem/yr) unrestricted release dose limit in **12 VAC 5-481-1160**. For radionuclides in a mixture, the "sum of fractions" rule applies; see **12 VAC 5-481-3690**. Refer to NRC NUREG-1727 '*NMSS Decommissioning Standard Review Plan*' for further information on application of the values in this table.

Table 13 was derived using the D and D screening code, Version 1, and its default input parameters. **Table 13** provides criteria which permit licensees to demonstrate compliance with the unrestricted release dose criterion in the license termination rule. The values correspond to screening "derived concentration guidelines" for each specific radionuclide based on the methodology described in NRC NUREG-1727 '*NMSS Decommissioning Standard Review Plan*'. Sites with building surface contamination levels below those listed in **Table 13** would be deemed acceptable for release for unrestricted use in accordance with the dose criteria in **12 VAC 5-481-1160**, provided that residual radioactivity has been reduced to ALARA levels. The table is intended for use as criteria to facilitate license termination for many simple routine decommissioning cases without a site-specific dose assessment. For facilities with contamination levels above those in **Table 13**, additional site-specific dose assessments may be necessary, and licensees should refer to NRC NUREG-1727 '*NMSS Decommissioning Standard Review Plan*' regarding acceptable methods for conducting the appropriate dose assessment.

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

dated July 1998, and NRC NUREG/CR - 5512, Vol. #3, 'Residual Radioactive Contamination From Decommissioning, Parameter Analysis,' dated April 25, 1996, can also be accessed through NRC's web site at www.nrc.gov.

Survey Record Requirements

Each survey record should include the following:

- A diagram of the area surveyed (See **Figure 16**);
- 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; and
- Name of the person making the evaluation and recording the results and date.

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

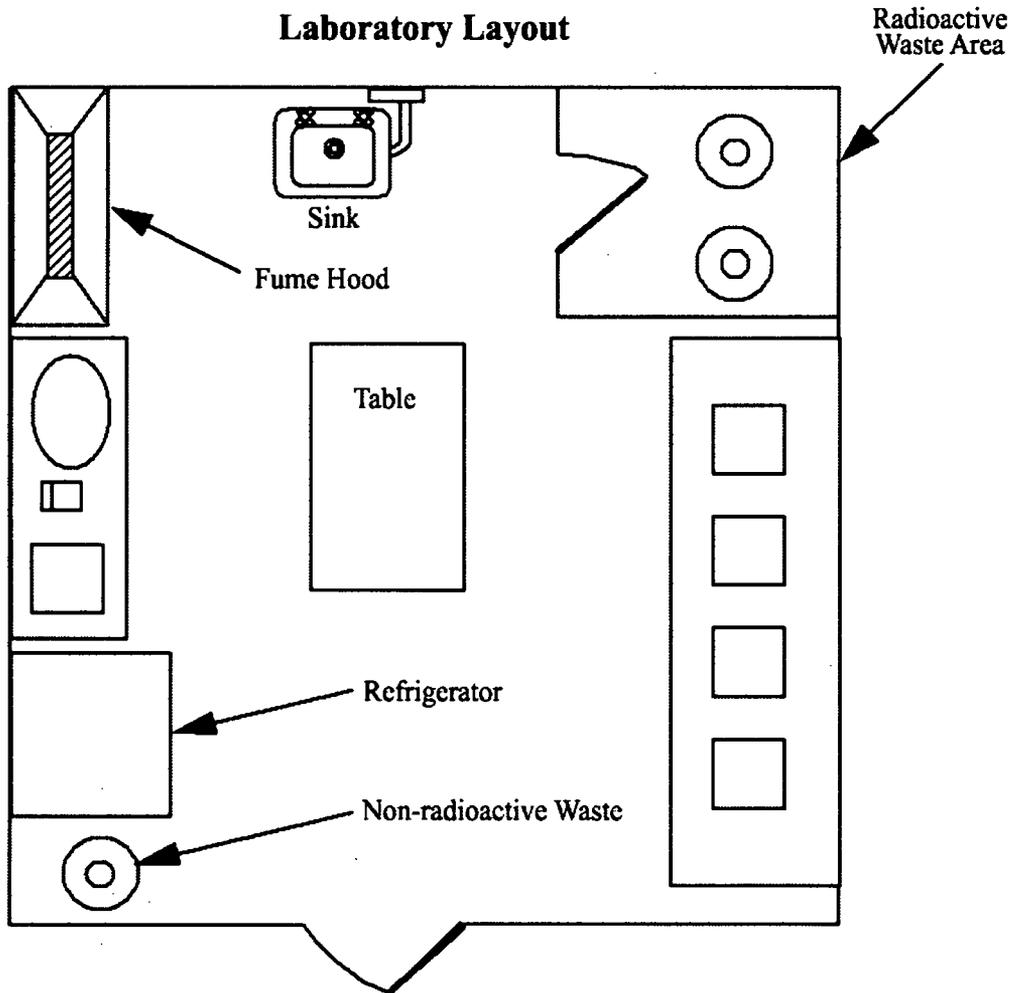


Figure 1: Laboratory Layout. This is an example of a laboratory survey map

Air Monitoring in the Workplace

Air sampling can be used to do the following:

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

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

Refer to NRC Regulatory Guide 8.25, Revision 1, 'Air Sampling in the Workplace' dated June 1992 and NRC NUREG - 1400, 'Air Sampling in the Workplace' dated September 1993 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*' dated December 1996, provides guidance on methods acceptable (calculation or COMPLY code) to the agency for compliance with the constraint on air emissions to the environment.

NRC Regulatory Guide 8.37, '*ALARA Levels for Effluents from Materials Facilities*,' dated July 1993, 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 or the number of procedures performed or other appropriate methods. The unmonitored effluents should not exceed 30% of the total estimated effluent releases or 10% of the permissible air effluent in **12 VAC 5-481-3690**, 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 **12 VAC 5-481-720** and **12 VAC 5-481-930**, respectively.

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

Bioassay Monitoring

Frequency of Required Bioassay Measurements

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

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

Bioassay measurements used for demonstrating compliance with the occupational dose limits should be conducted often enough to identify and quantify potential exposures and resultant intakes that, during any year, are likely to

collectively exceed 0.1 times the ALI. The 10% ALI criterion is consistent with **12 VAC 5-481-760**, which requires licensees to monitor intakes and assess occupational doses for exposed individuals who are likely to exceed 10% of the applicable limit (i.e., intakes likely to exceed 0.1 ALI for adults).

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

Routine Measurements

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

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

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

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

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

Special Monitoring

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

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

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

- NUREG-1727 '*NMSS Decommissioning Standard Review Plan*'
- Federal Register Notice, 'Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination,' Volume 63, Number 222, Page 64132, dated November 18, 1998
- NRC Regulatory Guide 4.20, 'Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors,' dated December 1996
- NRC Regulatory Guide 8.9, Revision 1, 'Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program,' dated July 1993
- NRC Regulatory Guide 8.23, Revision 1, 'Radiation Safety Surveys at Medical Institutions,' dated January 1981
- NRC Regulatory Guide 8.25, Revision 1, 'Air Sampling in the Workplace,' dated June 1992
- NRC Regulatory Guide 8.32, 'Criteria for Establishing a Tritium Bioassay Program,' dated July 1988
- NRC Regulatory Guide 8.37, 'ALARA Levels for Effluents from Materials Facilities,' dated July 1993
- NUREG - 1400, 'Air Sampling in the Workplace,' dated September 1993
- NUREG - 1549, 'Decision Methods for Dose Assessment to Comply With Radiological Criteria for License Termination,' dated July 1998
- NUREG/CR - 5512, Vol. #3, 'Residual Radioactive Contamination From Decommissioning, Parameter Analysis,' dated April 25, 1996
- NUREG/CR - 4884, 'Interpretation of Bioassay Measurements,' dated July 1987
- Additional References
- ANSI N13.1 (1969), 'Document to Sampling Airborne Radioactive Materials in Nuclear Facilities,' dated 1991
- ANSI N42.18, 'Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents,' 1991
- NCRP Commentary No. 3, 'Screening Techniques for Determining Compliance with Environmental Standards,' published in January 1989 and the addendum published in October 1989

Appendix R:

Leak Test Procedures

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

Frequency for Conducting Leak Tests of Sealed Sources

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

Procedure for Performing Leak Testing and Analysis

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

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

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

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

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

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

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

Appendix S:

Transportation

Part 1: Major DOT Regulations

Transportation

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

- Hazardous Materials Table: **49 CFR 172.101, App. A, Subpart B**, list of hazardous substances and reportable quantities (RQ), Table 2: Radionuclides
- Shipping Papers: **49 CFR 172.200-204**: General entries, description, additional description requirements, shipper's certification
- Package Markings: **49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324**: General marking requirements for non-bulk packagings, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging
- Package Labeling: **49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440**: General labeling requirements, prohibited labeling, radioactive materials, placement of labels, specifications for radioactive labels
- Placarding of Vehicles: **49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.510; 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556**: Applicability, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, specifications for RADIOACTIVE placards
- Emergency Response Information: **Subpart G, 49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604**: Applicability and general requirements, emergency response information, emergency response telephone number
- Training: **Subpart H, 49 CFR 172.702, 49 CFR 172.704**: Applicability and responsibility for training and testing, training requirements
- Shippers - General Requirements for Shipments and Packaging: **Subpart I, 49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.412, 49 CFR 173.415, 49 CFR 173.431, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.443, 49 CFR 173.448, 49 CFR 173.475, 49 CFR 173.476**: Definitions, general design requirements, additional design requirements for Type A packages, authorized Type A packages, activity limits for Type A packages, requirements for determining A₁ and A₂, table of A₁ and A₂ values for radionuclides, radiation level limitations, contamination control, general transportation requirements, quality control requirements prior to each shipment, approval of special form radioactive materials
- Radiation Protection Program for Shippers and Carriers: **Subpart I, 49 CFR 172.800, 49 CFR 172.802, 49 CFR 172.804**: Applicability of the radiation protection program, radiation protection program, record keeping, and notifications
- Carriage by Public Highway - General Information and Regulations: **Subpart A, 49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842**: Driver training, shipping paper, general requirements (secured against movement), Class 7 (radioactive) material.

Part 2: Sample Shipping Documents, Placards and Labels

Hazard Communications for Class 7 (Radioactive) Materials

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 \leq 0.5 mSv/hr (50 mrem/hr)	0.5 mSv/hr (50 mrem/hr) < surface radiation level \leq 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 \leq 1 [1 meter dose rate < 0.01 mSv/hr (1 mrem/hr)]	TI \leq 10 [1 meter dose rate < 0.1 mSv/hr (10 mrem/hr)] [Note: There is no package TI limit for exclusive-use]	
Notes:	<ul style="list-style-type: none"> 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):
 - The radionuclides in the package (with consideration of available space). Symbols (e.g., Co-60) are acceptable
 - 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.
 - 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))

- 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

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 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-light containers with less than an A₂ quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52. Also, for bulk packages of these materials, the orange panel marking with the UN identification number is not required.
- Placards are required any vehicle containing package with a Highway Route Controlled Quantity (HRCQ). In this case, the placard must be placed in a square background as shown below (see §173.507(a))

Radioactive Placard

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

Some Special Considerations/Exceptions for Placarding Requirements

- Domestically, substitution of the UN ID number for the word "RADIOACTIVE" on the placard is prohibited for Class 7 materials. However, some import shipments may have this substitution in accordance with international regulations.
- Bulk packages require the orange, rectangular panel marking containing the UN ID number, which must be placed adjacent to the placard (see §172.332) [NOTE: except for LSA/SCO exclusive use under §173.427, as above]
- If placarding for more than one hazard class, subsidiary placards must not display the hazard class number. Uranium Hexafluoride (UF₆) shipments ≥ 454 kg (1001 lbs) require both RADIOACTIVE and CORROSIVE (Class 8) placarding
- For shipments of radiography cameras in convenience overpacks, if the overpack does not require a RADIOACTIVE - YELLOW III label, vehicle placarding is not required (regardless of the label which must be placed on the camera)

Minimum Required Packaging For Class 7 (Radioactive) Materials				
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials				
Quantity:	< 70 Bq/g (< 0.002 Ci/g)	Limited Quantity (§173.421)	A ₁ /A ₂ value (§173.435)	1 rem/hr at 3 m. unshielded (§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}

- 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)
- Exclusive use required for strong-tight container shipments made pursuant to §173.427(b)(2)
- Subject to conditions in Certificate, if NRC package
- 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		

- The limits in this table do not apply to excepted packages - see 49 CFR 173.421-426
- Securely attached (to vehicle), access-limiting enclosure; package personnel barriers are considered as enclosures
- For nonfissile radioactive materials packages, the dimensionless number equivalent to maximum radiation level at 1m (3.3 feet) from the exterior package surface, in millirem/hour
- No dose limit is specified, but separation distances apply to Radioactive Yellow-II or Radioactive Yellow-III labeled packages
- Does not apply to private carrier wearing dosimetry if under radiation protection program satisfying 10 CFR 20 or 49 CFR 172 Subpart I
- 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 cm²
Sufficient measurements must be taken in the appropriate locations to yield representative assessments

& (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)

<p><i>The Basic Contamination Limits for All Packages: 49 CFR 173.443(a), Table 11</i></p>	<p>General Requirement: Non-fixed (removable) contamination must be kept as low as reasonably achievable (ALARA)</p>
	<p>&(: 0.4 Bq/cm² = 40 Bq/100 cm² = 1x10⁻⁵ :Ci/cm² = 2200 dpm/100 cm²</p>
	<p>" : 0.04 Bq/cm² = 4 Bq/100 cm² = 1x10⁻⁶ :Ci/cm² = 220 dpm/100 cm²</p>

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

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

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

Example Certificate Enclosed In/on Package, Included with the Packing List or Otherwise Forwarded with the Package)

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

(Signed) Radiation Safety Officer

Appendix T:
Waste Management Procedures

General Guidelines

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

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

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

Procedure for Disposal of Liquids Into Sanitary Sewerage

- Confirm that sewerage system is a public system, not a private sewerage system, septic system, or leach field.
- Confirm that the liquid waste being discharged is soluble or biological material that is readily dispersible in water.

- Calculate the amount of each radioisotope that can be discharged by using the information from prior, similar discharges and the information in **12 VAC 5-481-3690 ‘Virginia Radiation Protection Regulations’**.
- Make sure that the amount of each radioisotope does not exceed the monthly and annual discharge limits specified in **12 VAC 5-481-930** and **12 VAC 5-481-3690 ‘Virginia Radiation Protection Regulations’**.
- Record the date, radioisotope(s), estimated activity of each radioisotope, location where the material is discharged, and the initials of the individual discharging the waste.
- Liquid waste should be discharged only via designated sinks, toilets or release points.
- Discharge liquid waste slowly with water running from the faucet to dilute it.
- Survey the sink and surrounding work surfaces to confirm that no residual material or contamination remained in the sink or on work surfaces.
- Prior to leaving the area, decontaminate all areas or surfaces, if found to be contaminated.
- Maintain records of each radioisotope and its quantity and concentration that is released into the sanitary sewer system.

Commonwealth of Virginia
Radiation Protection Regulatory Guide



**Guidance for Medical Use of Radioactive
Material**

EPI-720 G

Virginia Department of Health
Radioactive Materials Program
109 Governor Street, Room 730
Richmond, VA 23219
Phone: (804) 864-8150

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 the **12 VAC 5-481 'Virginia Radiation Protection Regulations'** to delineate techniques used by staff in evaluating past specific problems or postulated accidents, and to provide guidance to applicants, licensees, or registrants. VAREGS are not substitutes for **12 VAC 5-481 'Virginia Radiation Protection Regulations'**; therefore, compliance with them is not required. Methods and solutions different from those set forth in this guide will be acceptable if they provide a basis for the Virginia Department of Health (VDH), Radioactive Materials Program, to determine if a radiation protection program meets the current rule and protects health and safety.

Comments and suggestions for improvements in this VAREG are encouraged 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/rad/RhP-Index.asp>.

This VAREG, '*Guidance for Medical Use of Radioactive Material*' has been developed to streamline the application process for a Medical Use of Radioactive Material License. A copy of the VDH Form, '*Application for Radioactive Material License for Medical Use*' is located in **Appendix A** of this guide.

Appendix D through **Z** provide examples, models and additional information that can be used when completing the application.

It typically takes 60-90 days for a license to be processed and issued if the application is complete. When submitting the application be sure to include the appropriate application fee listed in 12 VAC 5-490 for:

Category 7A: Teletherapy, HDR, or stereotactic radiosurgery (including mobile)

Category 7B: Broad scope except Teletherapy, HDR or stereotactic radiosurgery

Category 7C: Mobile Nuclear Medicine

Category 7D: Medical-all others, including SNM Pacemakers

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

- Use this regulatory guide to prepare the VDH Form, '*Application for Radioactive Material License for Medical Use*' (**Appendix A**).
- Complete VDH Form, '*Application for Radioactive Material License for Medical Use*' (**Appendix A**). See 'Contents of Application' of the guide for additional information.
- Include any additional attachments.

All supplemental pages should be submitted 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.
- Submit an original signed application along with attachments (if any).
- Submit the application fee (for new licenses only).
- Retain one copy of the license 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

AAPM	American Association of Physicists in Medicine
ALARA	as low as is reasonably achievable
ALI	annual limit on intake
AMP	Authorized Medical Physicist
ANP	Authorized Nuclear Pharmacist
ANSI	American National Standards Institute
AU	Authorized User
bkg	background
Bq	Becquerel
CFR	Code of Federal Regulations
Ci	Curie
cc	centimeter cubed
cm ²	centimeter squared
Co-57	cobalt-57
Co-60	cobalt-60
cpm	counts per minute
Cs-137	cesium-137
DAC	derived air concentration
DOT	United States Department of Transportation
dpm	disintegrations per minute
FDA	United States Food and Drug Administration
GM	Geiger-Mueller
GSR	gamma stereotactic radiosurgery
HDR	high dose-rate
I-125	iodine-125
I-131	iodine-131
IN	Information Notice
Ir-192	iridium-192
LDR	low dose-rate
mCi	millicurie
ml	milliliter
mR	milliroentgen
mrem	millirem
mSv	millisievert
NaI(Tl)	sodium iodide (thallium doped)
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OCR	optical character reader
OSL	optically stimulated luminescence dosimeters
P-32	phosphorus-32
Pd-103	palladium-103
PDR	pulsed dose-rate
QA	quality assurance
Ra-226	radium-226
RG	Regulatory Guide
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
SDE	shallow-dose equivalent
SI	International System of Units (abbreviated SI from the French Le Système Internationale d'Unites)
Sr-90	strontium-90
SSDR	Sealed Source and Device Registration

Sv	Sievert
Tc-99m	technetium-99m
TEDE	total effective dose equivalent
TLD	thermoluminescent dosimeters
U-235	uranium-235
VDH	Virginia Department of Health, Radioactive Materials Program
WD	written directive
12 VAC 5-481	Virginia Radiation Protection Regulations
μCi	microcurie
%	percent

PURPOSE OF GUIDE

This document provides guidance to an applicant in preparing a medical use of radioactive materials license application. It also provides guidance on VDH's criteria for evaluating a medical use license application. It is not intended to address the commercial aspects of manufacturing, distribution, and service of sources in devices. It does not specifically describe the possession and use of pacemakers, which are addressed in **12 VAC 5-481 'Virginia Radiation Protection Regulations', Part III, 'Licensing of Radioactive Materials.'**

The term "patient" is used to represent "patient" or "human research subject" throughout this guide. The term "applicant" is used when describing the application process and the term "licensee" is used when describing a regulatory requirement.

This guide addresses the wide variety of radionuclides used in medicine. Typical uses are:

- Diagnostic studies with unsealed radionuclides;
- Therapeutic administrations with unsealed radionuclides;
- Diagnostic studies with sealed radionuclides;
- Manual brachytherapy with sealed sources; and
- Therapeutic administrations with sealed sources in devices (i.e., teletherapy, remote afterloaders and gamma stereotactic radiosurgery units).

This guide describes the information needed to complete VDH Form, *'Application for Radioactive Material License for Medical Use'* (**Appendix A**). This guide does not directly address complete radiation safety and licensing guidance for uses specified under *12 VAC-5-481-2060, 'Other Medical Uses of Byproduct Material or Radiation from Byproduct Material.'* Therefore, VDH Radiation Protection Section staff should be contacted with questions regarding information not provided.

The format for each item number in this guide is as follows:

- **Rule** – references the requirements of **12 VAC 5-481 '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; and
- **Response from Applicant** – shows the appropriate item on the application and provides: response(s), offers the option of an alternative response, or indicates that no response is needed on that topic.

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 in accordance with agency guidelines. Submission of incomplete or inadequate information will result in delays in the

approval process for the license. Additional information will be requested when necessary to ensure that an adequate radiation safety program has been established. Such requests for additional information will delay completion of the application's review and may be avoided by a thorough study of the rule and these instructions prior to submitting the application.

12 VAC 5-481 'Virginia Radiation Protection Regulations' requires the applicant and/or licensee to develop, document, and implement procedures that will ensure compliance with the rule. The appendices describe radiation protection procedures. Each applicant should read the rule and procedures carefully and then decide if the procedure addresses specific radiation protection program needs at the applicant's facility. Applicants may adopt a procedure (e.g., **Appendix H, I, L, N, O, Q, R, T, U, V and X**) 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 **12 VAC 5-481-10**. 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 **12 VAC 5-481 '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 and is modeled on the Nuclear Regulatory Commission's (NRC) NUREG 1556, Volume 9. The VAREG shows the requirements in terms of the **12 VAC 5-481 'Virginia Radiation Protection Regulations'** and provides a user-friendly format to assist with the preparation of a medical use license application. Specific information has been included for technologies that are now more commonly used such as computerized remote afterloading brachytherapy and gamma stereotactic radiosurgery.

Applicants and licensees should be aware of other VAREGs that provide useful information for medical use licensees. For example, VAREG '*Guidance for Licenses of Broad Scope*' provides additional licensing guidance on medical use programs of broad scope.

LICENSES

VDH regulates the intentional internal or external administration of radioactive material, or the radiation from radioactive material, to patients or human research subjects for medical use. VDH issues three types of licenses for the use of radioactive material in medical practices and facilities. These are the general *in vitro* license, the specific license of limited scope, and the specific license of broad scope. These licenses are issued pursuant to **12 VAC 5-481 'Virginia Radiation Protection Regulations', Part III 'Licensing of Radioactive Materials'**.

VDH usually issues a single radioactive material license to cover an entire radionuclide program. A license including teletherapy may also contain the authorization for source material (i.e., depleted uranium) used as shielding in many teletherapy units. Although VDH may issue separate licenses to individual licensees for different medical uses, it does not usually issue separate licenses to different departments in a medical facility or to individuals employed by or with whom the medical facility has contracted. Only the facility's management may sign the license application.

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

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

- Statements, representations, and procedures contained in the application and in correspondence with VDH;
- Terms and conditions of the license; and
- **12 VAC 5-481 'Virginia Radiation Protection Regulations'**.

GENERAL IN VITRO LICENSE

In **12 VAC 5-481-430 G**, '*General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing*', VDH issues a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals to receive, acquire, possess, or use small quantities of certain radioactive material for *in vitro* clinical or laboratory tests not involving "medical use" (i.e., not involving administration to humans). A summary of the above rule is available from the VDH web-site located at <http://www.vdh.virginia.gov/rad/RHP-Index.asp> which explains the requirements for using the materials listed. If the general license alone meets the applicant's needs, only VDH Form, '*Certificate – In Vitro Testing With Radioactive Material Under General License*', needs to be filed. Medical-use licensees authorized pursuant to **12 VAC 5-481 'Virginia Radiation Protection Regulations, Part VII 'Use of Radionuclides in the Healing Arts'**, do not need to file the form.

VDH limits possession to a total of 200 microcuries of photon-emitting materials listed in **12 VAC 5-481-430 G** at any one time, at any one location of storage or use. The use of materials listed in **12 VAC 5-481-430 G** within the inventory limits of that section is subject only to the requirements of that section and not to the requirements of **12 VAC 5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation' and Part X, 'Notices, Instructions and Reports to Workers'**, except as set forth in **12 VAC 5-481-430 G**.

An applicant needing more than 200 microcuries of these materials must apply for a specific license and may request the increased inventory limit as a separate line item on VDH Form, '*Application for Radioactive Material License for Medical Use*'. This type of applicant generally requests an increased limit of 3 millicuries. If requesting an increased inventory

limit, the applicant will be subject to the requirements of *12 VAC 5-481* ‘**Virginia Radiation Protection Regulations**’, **Part IV ‘Standards for Protection Against Radiation**’, including the requirements for waste disposal and **Part X ‘Notices, Instructions and Reports to Workers**’.

SPECIFIC LICENSE OF LIMITED SCOPE

VDH issues specific medical licenses of limited scope to private or group medical practices and to medical institutions. A medical institution is an organization in which more than one medical discipline is practiced. In general, individual physicians or physician groups located within a licensed medical facility (e.g., hospital) may not apply for a separate license because *12 VAC 5- 481-450 A 2* refers to the applicant’s facilities. Since a physician group does not normally have control over the facilities, the hospital remains responsible for activities conducted on its premises and must apply for the license. On specific licenses of limited scope, the authorized users are individually listed in the license.

Radioactive material may be administered to patients on an inpatient (i.e., hospitalized) or outpatient basis. For patients to whom radioactive material is administered, who are not releasable under *12 VAC 5- 481-1870*, inpatient facilities are required. In general, facilities for private and group practices do not include inpatient rooms and, therefore, procedures requiring hospitalization of the patient cannot be performed.

A specific license of limited scope may also be issued to an entity requesting to perform mobile medical services [*12 VAC 5-481-1880, 12 VAC 5- 481-2040*]. A medical institution or a private or group practice may apply for authorization to use radioactive material in a mobile medical service.

SPECIFIC LICENSE OF BROAD SCOPE

Medical institutions that provide patient care and conduct research programs that use radionuclides for *in vitro*, animal, and medical procedures may request a specific license of broad scope in accordance *12 VAC 5-481* ‘**Virginia Radiation Protection Regulations**’, **Part III ‘Licensing of Radioactive Materials**’. The criteria for the various types of broad scope licenses are found in *12 VAC 5-480- 460*. Generally, VDH issues specific licenses of broad scope for medical use (i.e., licenses authorizing multiple quantities and types of radioactive material for unspecified uses) to institutions that (1) have experience successfully operating under a specific license of limited scope; and (2) are engaged in medical research and routine diagnostic and therapeutic uses of radioactive material. VAREG ‘*Guidance for Licenses of Broad Scope*’ offers additional guidance to applicants for a specific license of broad scope.

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

12 VAC 5-481-630, Radiation protection programs, states that "each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities" and "the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are...ALARA." This section also requires that licensees review the content of the radiation protection program and its implementation annually.

The following documents contain information, methods, and references useful to those who are establishing radiation protection programs to maintain radiation exposures at ALARA levels in medical facilities and provide VDH's position:

- NRC's RG 8.10, *'Operating Philosophy for Maintaining Occupational Radiation Exposures ALARA,'* and
- NRC's RG 8.18, *'Information Relevant to Ensuring That Occupational Radiation Exposures at Medical Institutions Will Be ALARA.'*

Background information on the ALARA philosophy and its application in the medical environment is contained in:

- NRC's NUREG-0267, *'Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions ALARA'* and
- NRC's NUREG-1134, *'Radiation Protection Training for Personnel Employed in Medical Facilities.'*

Information directly related to radiation protection standards in **12 VAC 5-481 '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.

WRITTEN DIRECTIVE (WD) PROCEDURES

12 VAC 5-481-1730 requires medical use licensees to develop, implement, and maintain written procedures to provide high confidence that before each administration requiring a WD, the patient's identity is verified and the administration is in accordance with the WD. This rule also specifies what, at a minimum, these procedures must address. **Appendix S** provides further information on developing these procedures.

RESEARCH INVOLVING HUMAN SUBJECTS

12 VAC 5-481-10 defines “*medical use*” to include the administration of radioactive material to human research subjects. Furthermore, *12 VAC 5-481-1670*, ‘Provisions for the protection of human research subjects’ addresses the protection of the rights of human subjects involved in research conducted by limited specific medical use licensees and broad scope medical use licensees.

Prior VDH approval is not necessary if the research is conducted, funded, supported, or regulated by federal agencies that have implemented the ‘Federal Policy for the Protection of Human Subjects’. Otherwise, the licensee must apply for a specific amendment and receive approval for the amendment before conducting such research. Whether or not a license amendment is required, licensees must obtain informed consent from human subjects and prior review and approval of the research activities by an ‘Institutional Review Board’ or equivalent under the meaning of these terms as defined and described in the ‘Federal Policy for the Protection of Human Subjects’. In accordance with *12 VAC 5-481-1670*, research involving human subjects shall be conducted only with radioactive materials listed in the license for the uses authorized in the license.

Licensees conducting human research using radioactive drugs, sealed sources, and/or devices are responsible for ensuring that, in addition to complying with *12 VAC 5-481-1670*, they comply with all other applicable VDH requirements and license conditions. Therefore, it is a licensee’s responsibility to ensure that:

- It is authorized to possess the materials and devices needed to participate in the research studies;
- The materials and devices to be used in the research are included in the specific medical uses authorized in the license;
- The procedures in the research protocols do not conflict with VDH regulatory and license requirements; and
- It is in compliance with *12 VAC 5-481-1670*, its license, and any other VDH and other federal regulatory requirements.

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 VDH or NRC regulatory requirements, as appropriate. The following table lists examples of regulatory authority.

Table 1: Who Regulates the Activity?

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

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

MANAGEMENT RESPONSIBILITY

VDH endorses the philosophy that effective radiation protection program management is vital to safe operations that comply with VDH regulatory requirements [see *12 VAC 5-481-1700*].

“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 in accordance with *12 VAC 5-481-450 and 12 VAC 5-481-1700*, a management representative (i.e., chief executive officer or delegate) must sign the submitted application acknowledging management’s commitments to and responsibility for the following:

- Radiation protection, security, and control of radioactive materials, and compliance with rule;
- Knowledge about the contents of the license application;
- Compliance with current VDH and United States Department of Transportation (DOT) regulations and the licensee’s operating and emergency procedures;
- Provision of adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that patients, the public, and workers are protected from radiation hazards;
- Appointment of a qualified individual who has agreed in writing to work as the RSO;
- Approval of qualified individual(s) to serve as Authorized Medical Physicists (AMPs), Authorized Nuclear Pharmacists (ANPs), and Authorized Users (AUs) for licensed activities.

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 F**.

APPLICABLE RULE

It is the applicant's or licensee's responsibility to obtain, read, and follow **12 VAC 5-481 'Virginia Radiation Protection Regulations'**.

The following parts of **12 VAC 5-481 'Virginia Radiation Protection Regulations'** contain requirements applicable to medical use licensees:

- Part I "General Provisions"
- Part III "Licensing of Radioactive Material"
- Part IV "Standards for Protection Against Radiation"
- Part VII "Use of Radionuclides in the Healing Arts"
- Part X "Notices, Instructions and Reports to Workers"
- Part XIII "Transportation of Radioactive Material"

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

HOW TO FILE

PAPER APPLICATION

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 Medical Use*' (**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.
- Submit an original, signed application.
- 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.
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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 **12 VAC 5-481 'Virginia Radiation Protection Regulations'** and must file a license application with:

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

LICENSE FEES

The appropriate fee must accompany each application or license amendment request. Refer to *12 VAC 5-490* to determine the amount of the fee. VDH will not issue the new license prior to fee receipt. Once technical review has begun, no fees will be refunded. Application fees will be charged regardless of VDH's disposition of an application or the withdrawal of an application.

Licensees are also subject to annual fees; refer to *12 VAC 5-490*.

Direct all questions about VDH's fees or completion of **Item 11** of VDH Form '*Application for Radioactive Material License for Medical Use*' (**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

This section explains, item by item, the information requested on VDH Form 'Application for Radioactive Material License for Medical Use' (Appendix A). Items 9.1 through 9.23 on the form request specific information about the proposed radiation safety program. To assist the applicant in submitting complete information on these items, the applicable rule citations are referenced in the discussion of each item.

Applicants must provide detailed information about the following:

- Proposed facilities and equipment;
- Training and experience of radioactive material users and the RSO;
- Delegation of authority to RSO;
- Financial assurance (if applicable);
- Mobile use of radioactive material (if applicable); and
- Procedures as indicated by this VAREG and VDH Form 'Application for Radioactive Material License for Medical Use' (Appendix A).

Procedures should provide for:

- Instruction of individuals in the procedures;
- Discussion of timeliness and frequency of conduct procedures;
- Periodic verification through observation, records review; or some other audit method, that individuals know the procedures and follow them; and
- Updating the procedures as necessary to accommodate changes in the license program, such as the introduction of new modalities (i.e., Remote Afterloaders, Teletherapy, Gamma Stereotactic Units).

Several appendices in this report present sample procedures that applicants may commit to follow or use to develop site specific procedures.

Item 1: Type of Application

On the application check the appropriate box and list the license number for renewal and amendments.

Response from Applicant:

<p>Item 1. Type Of Application (Check one box)</p> <p><input type="checkbox"/> New License <input type="checkbox"/> Renewal License Number</p>
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- 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 material; and
- Public health and safety are not compromised by the use of such materials.

As provided in *12 VAC 5-481-1690*, if the licensee's name or mailing address changes, and the name change does not constitute a transfer of control of the license as described in *12 VAC 5-481-1690*, a licensee must file a written notification with VDH no later than 30 days after the dates of the change(s). Otherwise, VDH's written consent must be given prior to the transfer.

Appendix D identifies the information to be provided about transferring control of a license.

Reference: Copies of NRC Information Notices and NUREGs including: IN 97-30, '*Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises*,' dated June 3, 1997, and NUREG-1556, Vol. 15, '*Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses*,' dated November 2000 can be accessed at NRC's web site, <http://www.nrc.gov>.

Notification of Bankruptcy Proceedings

Rule: *12 VAC 5-481- 490*

Criteria: *12 VAC 5-481- 490* states: "A licensee shall notify VDH in writing immediately of the filing of a voluntary or involuntary petition for bankruptcy for or against a licensee, identifying the bankruptcy court in which the petition was filed and the date of filing".

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 within 10 days 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 4: Address(es) Where Radioactive Material Will Be Used Or Possessed

Rule: 12 VAC 5-481-450 A 2; 12 VAC 5-481-1880

Pursuant to 12 VAC 5-481-450 A 2 and as referenced in VDH Form 'Application for Radioactive Material License for Medical Use' (Appendix A), Item 4, specify the street address, city, state and zip code or other descriptive address (e.g., on Highway 58, 5 miles east of the intersection of Highway 58 and State Route 16, Anytown, VA) for each facility. The descriptive address should be sufficient to allow a VDH inspector to find the facility location. A post office box address is not acceptable (see Figure 2). If radioactive material is to be used at more than one location under the license, the specific address (e.g., street and building) must be provided for each facility. If applying for a license for a mobile medical service as authorized pursuant to 12 VAC 5-481-1880, the applicant should refer to Item 9.17, 'Mobile Medical Service' and Appendix V of this report for specific licensing guidance.

A VDH license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., local zoning requirements; a local ordinance requiring registration of a radiation-producing device).
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As discussed in Item 7.2 'Recordkeeping for Decommissioning and Financial Assurance', licensees must maintain permanent records on where the licensed material was used or stored while the license was in effect. These records are important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). For medical use licensees, acceptable records include sketches and written descriptions of the specific locations where material is (or was) used or stored and any information relevant to spills (e.g., where contamination remains after cleanup procedures or when there is reasonable likelihood that contaminants may have spread), damaged devices, or leaking radioactive sources.

Response from Applicant:

Item 4. Address(es) Where Radioactive Material Will Be Used Or Possessed (Do not use P.O. Box)	
Address	Telephone Number (Include area code)
Address	Telephone Number (Include area code)
Address	Telephone Number (Include area code)
Address	Telephone Number (Include area code)
Address	Telephone Number (Include area code)
Is radioactive material used at other off-site locations? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If yes, please attach an additional sheet(s) with the address(es) and a list of activities to be conducted at each location of use.	

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

Rule: 12 VAC 5-481-450 A 1; 12 VAC 5-481-1700; 12 VAC 5-481-1750; 12 VAC 5-481-1760; 12 VAC 5-481-1770; 12 VAC 5-481-1780; 12 VAC 5-481-1790; 12 VAC 5-481-1910; 12 VAC 5-481-1940; 12 VAC-5-481-1980; 12 VAC 5-481-1990; 12 VAC 5-481-2000; 12 VAC 5-481-2010; 12 VAC 5-481-2030; 12 VAC 5-481-2040

Criteria: Licensees must ensure adequate oversight of their radioactive material program, and the RSO, AUs, AMPs, and ANPs must have adequate training and experience.

Discussion: 12 VAC 5-481-1700 provides the requirements regarding the authority and responsibilities for the radiation protection program, including those of the licensee's management and the RSO appointed by licensee management. Other personnel who have a role in the radiation protection program are AUs, AMPs, ANPs, and members of the Radiation Safety Committee (RSC) (if the licensee is required to establish a RSC). 12 VAC 5-481-450 A 1 requires that an applicant be qualified by training and experience to use licensed materials for the purposes requested in such a manner as to protect health and minimize danger to life or property. 12 VAC 5-481-1750, 12 VAC 5-481-1760, 12 VAC 5-481-1770, 12 VAC

5-481-1780, 12 VAC 5-481-1910, 12 VAC 5-481-1940, 12 VAC 5-481-1980, 12 VAC 5-481-1990, 12 VAC 5-481-2000, 12 VAC 5-481-2010, 12 VAC 5-481-2030, and 12 VAC 5-481-2040 give specific criteria for acceptable training and experience for AUs for medical use, ANPs, the RSO, and AMPs.

A résumé or a curriculum vitae is likely to be insufficient because such documents usually do not supply all the information needed to evaluate an individual's training and experience for VDH purposes. Applicants should ensure that they submit the specific training information required by VDH. VDH Form '*Training and Experience and Preceptor Statement*', found in **Appendix B**, provides a convenient format for submitting this information. **Appendix G** provides detailed instructions on completing VDH Form '*Training and Experience and Preceptor Statement*' (**Appendix B**).

Licenses are responsible for their radiation protection programs; it is essential that strong management control and oversight exist to ensure that licensed activities are conducted properly. The licensee's management must appoint an RSO, who agrees in writing to be responsible for implementing the radiation protection program, and must provide the RSO sufficient authority, organizational freedom, time, resources, and management prerogative to communicate with personnel and direct personnel regarding VDH rule and license provisions, including: identifying radiation safety problems; initiating, recommending, or providing corrective actions; stopping unsafe operations; and verifying the implementation of corrective actions. Nevertheless, the licensee retains the ultimate responsibility for the conduct of licensed activities.

Licenses that are authorized for two or more different types of uses of radioactive material under *12 VAC 5-481-1950, 12 VAC 5-481-2010, 12 VAC 5-481-2040* or two or more types of units under *12 VAC 5-481-2040*, must establish an RSC to oversee all uses of radioactive material permitted by the license. Membership of the committee must include an AU of each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an AU nor the RSO. The committee may include other members the licensee considers appropriate.

Licenses may contract for medical use services, including those involving patient services. However, the licensee should not assume that by hiring a contractor to provide certain services it has satisfied all regulatory requirements or that it has transferred responsibility for the licensed program to the contractor. Licensee management should ensure that adequate mechanisms for oversight are in place to determine that the radiation protection program, including training of contractor staff, is effectively implemented by the appropriate individuals.

Item 5.1: Radiation Safety Officer (RSO)

Rule: *12 VAC 5-481-450 A 1; 12 VAC 5-481- 1690; 12 VAC 5-481-1700; 12 VAC 5-481-1750; 12 VAC 5-481-1780; 12 VAC 5-481-1790; 12 VAC 5-481-2070*

Criteria: RSOs must have adequate training and experience. The training and experience requirements for the RSO are described in *12 VAC 5-481-1750* and allow for the following training pathways:

- Certification as provided in *12 VAC 5-481-1750* by one of the professional boards recognized by VDH and written attestation signed by a preceptor RSO as provided in *12 VAC 5-481-1750*.
- Classroom and laboratory training (200 hours) and 1 year of work experience as described in *12 VAC 5-481-1750* and written attestation signed by a preceptor RSO as provided in *12 VAC 5-481-1750*.
- For medical physicists, certification by a specialty board whose certification process has been recognized by VDH under *12 VAC 5-481-1760*, experience in radiation safety aspects of similar types of radioactive material use for which the individual has RSO responsibilities and written attestation signed by a preceptor RSO as provided in *12 VAC 5-481-1750*.
- Identification on the license as an AU, AMP, or ANP with experience in the radiation safety aspects of similar types of radioactive material use for which the individual has RSO responsibilities.

The licensee must also establish, in writing, the authority, duties, and responsibilities of the RSO. See **Appendix F** for typical duties and responsibilities of the RSO and a Model Delegation of Authority.

Discussion: The RSO is responsible for day-to-day oversight of the radiation protection program. In accordance with *12 VAC 5-481-1700*, the licensee must provide the RSO sufficient authority, organizational freedom, time, and resources to perform his or her duties. Additionally, the RSO must have a sufficient commitment from management to fulfill the duties and responsibilities specified in *12 VAC 5-481-1700* to ensure that radioactive materials are used in a safe manner. VDH requires the name of the RSO on the license, and an agreement in writing from the RSO, to ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation and assumes the responsibilities of an RSO.

Usually, the RSO is a full-time employee of the licensed facility. VDH has authorized individuals that are not employed by the licensee, such as a consultant, to fill the role of RSO or to provide support to the facility RSO. In order to fulfill the duties and responsibilities, the RSO should be on-site periodically to conduct meaningful, person-to-person interactions with licensee staff, commensurate with the scope of licensed activities, to satisfy requirements of *12 VAC 5-481-1700*.

Applicants are reminded of recentness of training requirements described in *12 VAC 5-481-1790*. Specifically, RSO applicants must have successfully completed the applicable training and experience criteria described in *12 VAC 5-481-1790* 'Virginia Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts' within 7 years preceding the date of the application. Alternatively, RSO applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Response from Applicant:

Item 5.1 Radiation Safety Officer (RSO) (Check all that apply and attach evidence of training and experience)

- We will provide the name of the proposed RSO and other potential designees who will be responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures. We will provide documentation showing delegation of authority to the Radiation Safety Officer.

Name: _____ Telephone Number (Include Area Code) (____) _____

AND ONE OF THE FOLLOWING

- We will provide the previous license number (if issued by VDH) or a copy of the license (if issued by the NRC or an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO.

OR

- We will provide a copy of the certification(s) for the board(s) approved by VDH and as applicable to the types of use for which he or she has RSO responsibility.

AND

We will provide a written attestation, signed by a preceptor RSO, that the above training and experience as specified in 12 VAC 5-481-1750 has been satisfactorily completed and that the individual has achieved a level of radiation safety knowledge sufficient to independently function as a RSO. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.

OR

- We will provide a description of the training and experience specified in 12 VAC 5-481-1750 demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.

AND

We will provide a written attestation, signed by a preceptor RSO, that the above training and experience as specified in 12 VAC 5-481-1750 has been satisfactorily completed and that the individual has achieved a level of radiation safety knowledge sufficient to independently function as a RSO. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.

AND, IF APPLICABLE

- We will provide a description of recent related continuing education and experience as required by 12 VAC 5-481-1790.

Notes:

- VDH Form 'Training and Experience and Preceptor Statement' may be used to document training and experience; see **Appendix B**. Detailed instructions for completing VDH Form 'Training and Experience and Preceptor Statement' are found in **Appendix G**.
- The licensee must notify VDH within 30 days if an RSO permanently discontinues his or her duties under the license [12 VAC 5-481-1690] and must request an amendment to change an RSO [12 VAC 5-481-1680].
- The licensee must notify VDH within 30 days if an RSO has a name change [12 VAC 5-481-1690].
- An AU, AMP, or ANP may be designated as the RSO on the license if the individual has training and experience with the radiation safety aspects of similar types of radioactive material use for which he or she has RSO responsibilities and, as required by 12 VAC 5-481-1700, has sufficient time, authority, organizational freedom, resources, and management prerogative to perform the duties.
- Descriptions of training and experience will be reviewed using the criteria listed above. VDH will review the documentation to determine if the applicable criteria in 12 VAC 481-1750 are met. If the training and experience do not appear to meet the criteria in 12 VAC 481-1750, VDH may request additional information from the applicant.

- The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's web page <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

Item 5.2: Authorized Users (AUs)

Rule: *12 VAC 5-481-450 A 1; 12 VAC 5-481-1690; 12 VAC 5-481-1710; 12 VAC 5-481-1780; 12 VAC 5-481-1790; 12 VAC 5-481-1910; 12 VAC 5-481-1940; 12 VAC 5-481-1980; 12 VAC 5-481-1990; 12 VAC 5-481-2000; 12 VAC 5-481-2010; 12 VAC 5-481-2030; 12 VAC 5-481-2040*

Criteria: Training and experience requirements for physician-AUs are described in *12 VAC 5-481-1910; 12 VAC 5-481-1940; 12 VAC 5-481-1980; 12 VAC 5-481-1990; 12 VAC 5-481-2000; 12 VAC 5-481-2010; 12 VAC 5-481-2030; 12 VAC 5-481-2040*

Discussion: An AU is defined in *12 VAC 5-481-10 'Definitions.'* The responsibilities of AUs involved in medical use include the following:

- Radiation safety commensurate with use of radioactive material;
- Administration of a radiation dose or dosage and how it is prescribed;
- Direction of individuals under the AU's supervision in the preparation of radioactive material for medical use and in the medical use of radioactive material; and
- Preparation of written directives, if required.

12 VAC 5-481-1780 provides that experienced AUs who are named on a VDH, NRC or another Agreement State license or permit in the preceding seven years are not required to comply with the training requirements in **12 VAC 5-481 'Virginia Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts'** to continue performing those medical uses.

Technologists, therapists, or other personnel may use radioactive material for medical use under an AU's supervision in accordance with *12 VAC 5-481-1710, 'Supervision,'* and in compliance with applicable FDA, other Federal, and State requirements (*12 VAC 5-481-1670*). Examples include FDA requirements for conduct of certain types of clinical research after submission of applications for INDs (Investigational New Drugs) and under the auspices of a Radioactive Drug Research Committee (*21 CFR 361.1*).

There is no VDH requirement that an AU must provide an interpretation of a diagnostic image or results of a therapeutic procedure. VDH recognizes that the AU may or may not be the physician who interprets such studies. Additionally, **12 VAC 5-481 'Virginia Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts'** does not restrict who can read and interpret diagnostic scans or the results of therapeutic procedures involving the administration of radioactive material to individuals.

AUs for Non-Medical Uses: For *in vitro* studies, animal research, calibration of survey instruments, and other uses that do not involve the intentional exposure of humans, the list of proposed AUs should include the individuals who will actually be responsible for the safe use of the radioactive material for the requested use.

An applicant should note which user will be involved with a particular use by referring to **Item 5.2** of the application and providing the user's training and experience.

Authorized non-medical use or uses that do not involve the intentional exposure of humans (e.g., *in vitro* and animal research, calibration, dosimetry research) will be reviewed on a case-by-case basis.

Applicants are reminded of recentness of training requirements described in **12 VAC 5-481-1790**. Specifically, physician-AU applicants must have successfully completed the applicable training and experience criteria described in **12 VAC 5-481 'Virginia Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts'** within 7 years preceding the date of the application. Alternatively, physician-AU applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Note: Licensees should designate at least one authorized user for each type of radioactive material requested in Item 7.1.

Response from Applicant:

Item 5.2 Authorized Users (AU) (Check all that apply and attach evidence of training and experience)

- We will attach a list of each proposed authorized user with the types and quantities of licensed material to be used.

AND ONE OF THE FOLLOWING FOR EACH AU

- We will provide the previous license number (if issued by VDH) or a copy of the license (if issued by the NRC or an Agreement State) on which the physician was specifically named as an AU for the uses requested.

OR

- We will provide a copy of the certification(s) for the board(s) approved by VDH and as applicable to the use requested.

AND

We will provide a written attestation, signed by a preceptor AU, that the training and experience as specified in 12 VAC 5-481-1910; 12 VAC 5-481-1940; 12 VAC 5-481-1980; 12 VAC 5-481-2010; 12 VAC 5-481-2040, as applicable, has been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized user. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.

OR

- We will provide a description of the training and experience as specified in 12 VAC 5-481-1910; 12 VAC 5-481-1940; 12 VAC 5-481-1980; 12 VAC 5-481-2010; 12 VAC 5-481-2030; 12 VAC 5-481-2040, as applicable, demonstrating that the proposed AU is qualified by training and experience for the use requested. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.

AND

We will provide a written attestation, signed by a preceptor AU, that the above training and experience as specified in 12 VAC 5-481-1910; 12 VAC 5-481-1940; 12 VAC 5-481-1980; 12 VAC 5-481-2010; 12 VAC 5-481-2040 as applicable, has been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized user. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.

AND, IF APPLICABLE

- We will provide a description of recent related continuing education and experience as required by 12 VAC 5-481-1790.

Notes:

- VDH Form 'Training and Experience and Preceptor Statement' may be used to document training and experience; see **Appendix B**. Detailed instructions for completing VDH Form 'Training and Experience and Preceptor Statement' are found in **Appendix G**.
- Licensees must notify VDH within 30 days if an AU permanently discontinues his or her duties under the license or has a name change under **12 VAC 5-481-1690**.
- Descriptions of training and experience will be reviewed using the criteria listed above. VDH will review the documentation to determine if the applicable criteria in **12 VAC 5-481 'Virginia Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts'** are met. If the training and experience do not appear to meet the criteria, VDH may request additional information from the applicant.
- The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's web page <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

Item 5.3: Authorized Nuclear Pharmacist (ANP)

Rule: *12 VAC 5-481-450 A 1; 12 VAC 5-481-1690; 12 VAC 5-481-1710; 12 VAC 5-481-1770; 12 VAC 5-481-1780; 12 VAC 5-481-1790*

Criteria: Training and experience requirements for ANPs are described in *12 VAC 5-481-1770*.

Discussion: An ANP is defined in *12 VAC 5-481-10 'Definitions.'* At many licensed medical facilities, an ANP is directly involved with the preparation and administration of radiopharmaceuticals.

Technologists, or other personnel, may prepare radioactive material for medical use under an ANP's supervision in accordance with *12 VAC 5-481-1710, 'Supervision,'* and in compliance with applicable U.S. Food and Drug Administration (FDA), other Federal, and State requirements [*12 VAC 5-481-1670*]. Preparation of radioactive material for medical use may also be performed under the supervision of a physician who is an authorized user.

Applicants are reminded of recentness of training requirements described in *12 VAC 5-481-1790*. Specifically, nuclear pharmacist applicants must have successfully completed the applicable training and experience criteria described in **12 VAC 5-481 'Virginia Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts'** within 7 years preceding the date of the application. Alternatively, nuclear pharmacist applicants must have had related continuing education and experience since initially completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Response from Applicant:

Item 5.3 Authorized Nuclear Pharmacist (ANP) (Check all that apply and attach evidence of training and experience)

Not applicable

We will provide the name(s) of the authorized nuclear pharmacist(s).

AND ONE OF THE FOLLOWING FOR EACH ANP

We will provide the previous license number (if issued by VDH) or a copy of the license (if issued by the NRC or an Agreement State) on which the individual was specifically named ANP.

OR

We will provide a copy of the certification(s) for the radiopharmacy board(s) approved by VDH.

AND

We will provide a written attestation, signed by a preceptor ANP, that the training and experience as specified in 12 VAC 5-481-1770 has been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.

OR

We will provide a description of the training and experience specified in 12 VAC 5-481-1770 demonstrating that the proposed ANP is qualified by training and experience. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.

AND

We will provide a written attestation, signed by a preceptor ANP, that the training and experience as specified in 12 VAC 5-481-1770 has been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.

AND, IF APPLICABLE

We will provide a description of recent related continuing education and experience as required by 12 VAC 5-481-1790.

Notes:

- VDH Form 'Training and Experience and Preceptor Statement' may be used to document training and experience; see **Appendix B**. Detailed instructions for completing VDH Form 'Training and Experience and Preceptor Statement' are found in **Appendix G**.
- Licensees must notify VDH within 30 days if an ANP permanently discontinues his or her duties under the license or has a name change under **12 VAC 5-481-1690**.
- Descriptions of training and experience will be reviewed using the criteria listed above. VDH will review the documentation to determine if the applicable criteria in **12 VAC 5-481 'Virginia Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts'** are met. If the training and experience do not appear to meet the criteria in **12 VAC 5-481 'Virginia Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts'**, VDH may request additional information from the applicant.
- The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's web page <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

Item 5.4: Authorized Medical Physicist (AMP)

Rule: *12 VAC 5-481-450 A 1; 12 VAC 5-481-1690; 12 VAC 5-481-1760; 12 VAC 5-481-1780; 12 VAC 5-481-1790*

Criteria: Training and experience requirements for AMPs are described in *12 VAC 5-481-1760*.

Discussion: An AMP is defined in *12 VAC 5-481-10*, “*Definitions*.” At many licensed medical facilities conducting radiation therapy treatments, an AMP is directly involved with the calculation and administration of the radiation dose. The American Association of Physicists in Medicine (AAPM) suggests that a medical physicist limit his or her involvement in radiation therapy to areas for which he or she has established competency.

Applicants are reminded of recentness of training requirements described in *12 VAC 5-481-1790*. Specifically, medical physicist applicants must have successfully completed the applicable training and experience criteria described in **12 VAC 5-481 ‘Virginia Radiation Protection Regulations’, Part VII ‘Use of Radionuclides in the Healing Arts’** within 7 years preceding the date of the application. Alternatively, medical physicist applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Response from Applicant:

ITEM 5.4. AUTHORIZED MEDICAL PHYSICIST (AMP) (Check all that apply and attach evidence of training and experience)

Not applicable

**COMPLETE ONLY IF REQUESTING LICENSE AUTHORIZATION FOR:
HDR, GAMMA STEREOTACTIC RADIOSURGERY UNIT, TELETHERAPY OR OPHTHALMIC USE**

We will provide the name(s) of the authorized medical physicist(s).
AND ONE OF THE FOLLOWING FOR EACH AMP

We will provide the previous license number (if issued by VDH) or a copy of the license (if issued by the NRC or an Agreement State) on which the individual was specifically named AMP.
OR

We will provide a copy of the certification(s) for the board(s) approved by VDH.
AND

We will provide a written attestation, signed by a preceptor AMP, that the training and experience as specified in 12 VAC 5-481-1760 has been completed and the individual has achieved a level of competency sufficient to function independently as an authorized medical physicist. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.
OR

We will provide a description of the training and experience specified in 12 VAC 5-481-1760 demonstrating that the proposed AMP is qualified by training and experience. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.
AND

We will provide a written attestation, signed by a preceptor AMP, that the above training and experience as specified in 12 VAC 5-481-1760 has been completed and the individual has achieved a level of competency sufficient to function independently as an authorized medical physicist. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.
AND, IF APPLICABLE

We will provide a description of recent related continuing education and experience as required by 12 VAC 5-481-1790.

Notes:

- VDH Form 'Training and Experience and Preceptor Statement' may be used to document training and experience; see **Appendix B**. Detailed instructions for completing VDH Form 'Training and Experience and Preceptor Statement' are found in **Appendix G**.
- Licensees must notify VDH within 30 days if an AMP permanently discontinues his or her duties under the license or has a name change **12 VAC 5-481-1690**.
- Descriptions of training and experience will be reviewed using the criteria listed above. VDH will review the documentation to determine if the applicable criteria in **12 VAC 5-481 'Virginia Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts'** are met. If the training and experience do not appear to meet the criteria in **12 VAC 5-481 'Virginia Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts'**, VDH may request additional information from the applicant.
- The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's web page <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

Item 6: Training for Individuals Working in or Frequenting Restricted Areas

Rule: *12 VAC 5-481-2270; 12 VAC 5-481-1960; 12 VAC 5-481-2010; 12 VAC 5-481-2040; 12 VAC 5-481-2070*

Criteria: Individuals working with or in the vicinity of licensed material must have adequate safety instruction as required by *12 VAC 5-481* ‘Virginia Radiation Protection Regulations’, Part VII ‘Use of Radionuclides in the Healing Arts’ and Part X ‘Notices, Instructions and Reports to Workers; Inspections’. For individuals who, in the course of employment, are likely to receive in a year an occupational dose of radiation over 1 mSv (100 mrem), the licensee must provide annual safety instructions as required in *12 VAC 5-481-2270*. Additional requirements for training in radiation safety for individuals involved with therapeutic treatment of patients are described in *12 VAC 5-481-1960*, *12 VAC 5-481-2010*, and *12 VAC 5-481-2040*. Records of safety instruction provided must be maintained in accordance with *12 VAC 5-481-2070*. *12 VAC 5-481-1710* requires the licensee’s AUs and ANPs to provide safety instruction to all personnel using radioactive material under their supervision.

Discussion: AUs, ANPs, AMPs, RSOs, and their supervised employees are most likely to receive doses in excess of 1 mSv (100 mrem) in a year. However, licensees also must evaluate potential radiation doses received by any individual working in or frequenting restricted areas. All individuals working with or around licensed materials should receive safety instruction commensurate with their assigned duties, and if it is likely that they could receive doses over 1 mSv (100 mrem) in a year, they must receive annual instruction as specified by *12 VAC 5-481-2270*. For example, a licensee might determine that housekeeping staff, while not likely to receive doses over 1 mSv (100 mrem), should be informed of the nature of the licensed material and the meaning of the radiation symbol, and instructed not to touch the licensed material and to remain out of the room if the door to the licensed material storage location is open. Providing minimal instruction to ancillary staff (e.g., housekeeping, security, etc.) may assist in controlling abnormal events, such as loss of radioactive material.

In addition to safety instruction required by *12 VAC 5-481-2270* and in accordance with *12 VAC 5-481-1960*, *12 VAC 5-481-2010*, and *12 VAC 5-481-2040*, the licensee must provide radiation safety instruction to personnel (e.g., nurses) caring for patients undergoing radiopharmaceutical therapy or implant therapy who cannot be released in accordance with *12 VAC 5-481-1870*. This safety instruction must be commensurate with the duties of the personnel and include safe handling, patient control, visitor control, contamination control, waste control, and notification of the RSO and the AU if the patient has a medical emergency or dies.

In accordance with *12 VAC 5-481-1710*, individuals working with licensed material under the supervision of an AU must receive instruction on the licensee’s written radiation protection procedures, written directive procedures, and VDH rule and license conditions with respect to the use of radioactive material.

In accordance with *12 VAC 5-481-1710*, a licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an ANP or an AU shall instruct supervised individuals in the preparation of radioactive material for medical use and require the individuals to follow their instructions, the licensee's written radiation protection procedures, the license conditions, and VDH rule. *12 VAC 5-481-1710* states that a licensee that permits supervised activities under paragraph *12 VAC 5-481-1710* is responsible for the acts and omissions of the supervised individuals.

Procedures describing the training programs are provided in **Appendix H**.

Response from Applicant:

<p>Item 6. Training For Individuals Working In or Frequenting Restricted Areas (Check one box)</p> <p><input type="checkbox"/> We will follow the training programs described in Appendix H of VAREG 'Guidance for Medical Use of Radioactive Material.'</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will develop and implement and maintain a training program that will meet the criteria in the section titled 'Training for Individuals Working in or Frequenting Restricted Areas' of VAREG "Guidance for Medical Use of Radioactive Material." (Description is attached)</p>
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Item 7: Radioactive Material

Rule: *12 VAC 5-481-440; 12 VAC 5-481-450; 12 VAC 5-481-490; 12 VAC 5-481-1680; 12 VAC 5-481-1830; 12 VAC 5-481-1900; 12 VAC 5-481-1920; 12 VAC 5-481-1950; 12 VAC 5-481-2010; 12 VAC 5-481-2020; 12 VAC 5-481-2040 and 12 VAC 5-481-2060*

Criteria: *12 VAC 5-481 'Virginia Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts'* divides radioactive material for medical use into the following types of use:

- 12 VAC 5-481-1900* Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is Not Required
- 12 VAC 5-481-1920* Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is Not Required
- 12 VAC 5-481-1950* Use of Unsealed Radioactive Material for Which a Written Directive is Required
- 12 VAC 5-481-2010* Use of Sealed Sources for Manual Brachytherapy
- 12 VAC 5-481-2020* Use of Sealed Sources for Diagnosis
- 12 VAC 5-481-2040* Use of a Sealed Source(s) in a Device for Therapy-Teletherapy Unit
- 12 VAC 5-481-2040* Use of a Sealed Source(s) in a Device for Therapy-Remote Afterloader Unit
- 12 VAC 5-481-2040* Use of a Sealed Source(s) in a Device for Therapy-Gamma Stereotactic Radiosurgery Unit
- 12 VAC 5-481-2060* Other Medical Uses of Radioactive Material or Radiation from Radioactive Material

Discussion: This section contains four subsections:

- **Item 7.1: Radioactive Material, Chemical & Physical Form, Possession Limit & Type of Use**

This subsection provides a discussion of the various types of use that can be authorized under a license for medical use of radioactive material and detailed instructions for requesting authorization for each type of use;

- **Item 7.2: Recordkeeping for Decommissioning and Financial Assurance**

This subsection details information that all licensees are required to maintain that is important to decommissioning;

- **Item 7.3: Sealed Sources and Devices**

This subsection provides information on how to make a determination if sealed sources and devices are acceptable for medical use of radioactive material; and

- **Item 7.4: Disposition of Material and Termination of License**

This subsection provides instructions on how to terminate licensed activities and properly document the disposition of the radioactive material.

Item 7.1: Radioactive Material, Chemical & Physical Form, Possession Limit & Type of Use

Rule: *12 VAC 5-481-430 G; 12 VAC 5-481-440; 12 VAC 5-481-450; 12 VAC 5-481-1900; 12 VAC 5-481-1920; 12 VAC 5-481-1950; 12 VAC 5-481-2010; 12 VAC 5-481-2020; 12 VAC 5-481-2040 and 12 VAC 5-481-2060*

Criteria: *12 VAC 5-481 'Virginia Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts'*, divides radioactive material for medical use into seven types of use *12 VAC 5-481-1900; 12 VAC 5-481-1920; 12 VAC 5-481-1950; 12 VAC 5-481-2010; 12 VAC 5-481-2020; 12 VAC 5-481-2040 and 12 VAC 5-481-2060.*

Discussion: For *in vitro* use exceeding general license limits under *12 VAC 5-481-430 G*, calibration sources exceeding the exemptions listed is *12 VAC 5-481-1830*, uptake, dilution and excretion studies under *12 VAC 5-481-1900*, and imaging and localization studies under *12 VAC 5-481-1920*, the applicant should select the type of use.

The use of unsealed radioactive material in therapy (*12 VAC 5-481-1950*) involves administering a radiopharmaceutical, either orally or by injection, to treat or palliate a particular disease. The most common form of radiopharmaceutical therapy is the treatment of hyperthyroidism with iodine-131 (I-131) sodium iodide. Other therapeutic procedures include ablation of thyroid cancer metastasis, treatment of malignant effusions, treatment of polycythemia vera and leukemia, palliation of bone pain in cancer patients, and radiation synovectomy for rheumatoid arthritis patients. For *12 VAC 5-*

481-1950, the applicant should select the box and enter the maximum quantity (in curies) of radioactive material to be possessed.

If only requesting a specific radioisotope for therapy use under *12 VAC 5-481-1950*, the applicant must provide a detailed description of radiopharmaceutical, form, route of administration and therapeutic use (see **Table 2**).

Table 2: Radiopharmaceuticals Used in Therapy

Radiopharmaceutical	Form	Route of Administration	Therapeutic Use
I-131 sodium iodide	solution/ capsules	oral	Hyperthyroidism Thyroid carcinoma Whole body scan for thyroid metastasis (diagnostic)
I-131 Tositumomab	solution	IV	Non-Hodgkin's lymphoma
phosphorus-32 (P-32) chromic phosphate	colloidal suspension	intraperitoneal or intrapleural cavity injection	Peritoneal or pleural effusions
P-32 sodium phosphate	solution	oral or IV	Polycythemia vera leukemia
strontium-89 chloride	solution	IV	Skeletal metastasis
samarium-153 EDTMP	solution	IV	Skeletal metastasis
rhenium-186 HEDP	solution	IV	Skeletal metastasis
tin-117m DTPA	solution	IV	Skeletal metastasis
dysprosium-165 FHMA	aggregate in solution	IV	Rheumatoid arthritis
yttrium-90 FHMA	aggregate in solution	IV	Rheumatoid arthritis
yttrium-90 Ibritumomab tiuxetan	solution	IV	Non-Hodgkin's lymphoma

For manual brachytherapy under *12 VAC 5-481-2010* several types of treatments are available. These may include:

- Interstitial Treatment of Cancer. The following sources are routinely used:
 - Cs-137 and Co-60 as a sealed source in needles and applicator cells;
 - iridium-192 (Ir-192) as seeds encased in nylon ribbon;
 - gold-198 (Au-198) as a sealed source in seeds; and
 - iodine-125 (I-125), and palladium-103 (Pd-103) as a sealed source in seeds used for permanent implants.
- Eye Plaque Implants. The eye plaque consists of a curved soft plastic insert that has a series of grooves molded into the rear convex surface that are designed to hold radioactive seeds. After the plastic insert is loaded with the

seeds, a solid gold cover, matched in size to the insert, is placed over the convex surface of the insert and cemented in place to seal the seeds into a fixed array within the plaque. The insert is completely surrounded by the gold cover except for the concave surface that is placed against the eye. When used with I-125 and Pd-103 seeds, the gold cover provides considerable shielding of the normal tissues surrounding the eye and limits the external dose rates surrounding the patient. Although not implanted into the tumor, because the plaque is placed in the orbit of the eye over the tumor site and sutured to the sclera of the eye to stabilize its position on the tumor while in the orbit, this is considered interstitial, not topical, treatment.

- Intracavitary Treatment of Cancer. Intraluminal use is considered analogous to intracavitary use. The following sources are routinely used for the intracavitary treatment of cancer:
 - Cs-137 and Co-60 as a sealed source in needles and applicator cells;
 - Ir-192 and Pd-103 seeds.
- Topical (Surface) Applications. The following sources are routinely used for topical applications:
 - Cs-137 and Co-60 as sealed sources in needles and applicator cells;
 - Sr-90 as a sealed source in an applicator for treatment of superficial eye conditions.

For use of Sr-90 in ophthalmic eye applicators only, as referenced in *12 VAC 5-481-2010*, applicant should select the box and provide the following information:

- the maximum quantity (in curies) of radioactive material to be possessed;
- the sealed source and device registration number for each sealed source and/or device;
- the sealed source manufacturer or distributor model number, and
- the device manufacturer or distributor model number.

For *12 VAC 5-481-2010* material, the applicant should select the box, and provide the following information:

- the maximum quantity (in curies) of radioactive material to be possessed;
- the sealed source and device registration number for each sealed source and/or device;
- the sealed source manufacturer or distributor model number, and
- the device manufacturer or distributor model number.

For *12 VAC 5-481-2020* material, the applicant should select the box, and provide the following information:

- the maximum quantity (in curies) of radioactive material to be possessed;
- the sealed source and device registration number for each sealed source and/or device;
- the sealed source manufacturer or distributor model number, and
- the device manufacturer or distributor model number.

Examples of *12 VAC 5-481-2020* uses include I-125, americium-241, or gadolinium-153 as a sealed source in a device for bone mineral analysis and I-125 as a sealed source in a portable imaging device.

For *12 VAC 5-481-2040* material, the applicant should select the box(es) for each desired modality (i.e., teletherapy, remote afterloader unit, or gamma stereotactic radiosurgery unit), and provide the following information:

- the maximum quantity (in curies) of radioactive material to be possessed;
- the sealed source and device registration number for each sealed source and/or device;
- the sealed source manufacturer or distributor model number, and
- the device manufacturer or distributor model number.

For sealed sources used in devices, an applicant may wish to request two sources, one to be used in the device and one to be stored in its shipping container, to accommodate the total quantity of material in the licensee's possession during replacement of the source in the device. Under *12 VAC 5-481-440*, the maximum activity for a single source or source loading may not exceed the activity specified by the manufacturer for the specific device and source combination as stated in the SSDR. However, it is permissible to request a maximum activity for the source in the shipping container, that exceeds the maximum activity allowed in the device. To request this authorization, applicants should provide certification that the source transport container is approved for the requested activity. A source that is received with a higher activity than permitted in the device must be allowed to decay to or below the device source activity limit prior to installation in the device.

12 VAC 5-481-2060 Other Medical Uses of Radioactive Material or Radiation from Radioactive Material (e.g., Emerging Technology)

Applicants must apply for authorization to use radioactive material, or radiation therefrom, in medical applications under *12 VAC 5-481-2060* when the desired type of use isn't covered elsewhere in *12 VAC 5-481 'Virginia Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts'* Use of radioactive material in a source or device after approval by the U.S. Food and Drug Administration (e.g., under an investigational device exemption or an investigational new drug exemption) does not preclude the necessity for applicants to obtain a VDH license for the radioactive material. For *12 VAC 5-481-2060* material, the applicant should attach a detailed description of the radioactive material (i.e., radionuclide, form, and maximum quantity in curies) and intended use along with the following information required by *12 VAC 5-481-1680*:

- Radiation safety precautions and instructions;
- Training and experience of proposed users;
- Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and
- Calibration, maintenance and repair of instruments and equipment necessary for radiation safety.

If the material is a sealed source, also provide the following:

- the sealed source and device registration number for each sealed source and/or device;
- the sealed source manufacturer or distributor model number, and
- the device manufacturer or distributor model number.

For information regarding the licensing of emerging technologies, licensees should consult the NRC's web page at: www.nrc.gov/materials/miau/med-use-toolkit.html.

Type A broad scope licensees are exempted under *12 VAC 5-481-460* from selected requirements in *12 VAC 5-481-1680* regarding emerging technologies. However, broad scope licensees should ensure that the quantity of radioactive material needed for the proposed use is authorized on their license or apply for an increase if it is not. Broad scope licensees should refer to NRC's IN 99-024, '*Broad-Scope Licensees Responsibilities for Reviewing and Approving Unregistered Sealed Sources and Devices.*'

Non-Medical Use of Radioactive Material

The applicant should check the "Other radioactive material" box and provide a detailed description for items that need to be listed (e.g., depleted uranium for linear accelerator shielding, survey meter calibrations with NIST traceable brachytherapy sources, dosimetry system constancy check source). Sources that are authorized by *12 VAC 5-481-1830*, '*Authorization for calibration and references sources*', should *not* be listed. If applicable, the applicant should request authorization to possess depleted uranium (i.e., uranium depleted in uranium-235) in quantities sufficient to include shielding material in both the device(s) and source containers used for source exchange. The applicant should review the manufacturer's specifications for each device specified in the license request to determine: (1) if depleted uranium is used to shield the source(s) within the device; and (2) the total quantity of depleted uranium present in the device (in kilograms). The applicant should also consult the manufacturer's specifications or the source supplier to determine if depleted uranium is contained in shielding source containers used during source exchange, as well as the total quantity of depleted uranium in such containers (in kilograms).

Response from Applicant:

Item 7.1 Purpose(s) For Which Licensed Radioactive Material Will Be Used. (Attach additional pages if necessary)

Type of Use – Check Box if Use is Desired	Chemical and Physical Form	Maximum Amount (Curies)	Sealed Source Manufacturer or Distributor Model Number	Device Manufacturer or Distributor Model Number
<input type="checkbox"/> Use of Radioactive Material for Certain In-Vitro Clinical or laboratory testing if maximum activity exceeds 200 μ Ci 12 VAC 5-481-430(G)	Any	As needed	N/A	N/A
<input type="checkbox"/> Use of Calibration, Transmission, and Reference Sources not included in 12 VAC 5-481-1830 (e.g., bone densitometry sources, fluorine-18 calibration sources)	Attach a detailed description of the radioactive material and intended use.		N/A	N/A
<input type="checkbox"/> Unsealed Radioactive Material for Uptake, Dilution and Excretion Studies for Which a Written Directive is not Required 12 VAC 5-481-1900	Any	As needed	N/A	N/A
<input type="checkbox"/> Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is not Required 12 VAC 5-481-1920	Any	As needed	N/A	N/A
<input type="checkbox"/> Unsealed Radioactive Material for Which a Written Directive is Required 12 VAC 5-481-1950	Any		N/A	N/A
<input type="checkbox"/> Unsealed Radioactive Material for Which a Written Directive is Required Specific radiopharmaceuticals 12 VAC 5-481-1950	For this type of use attach a detailed description of radiopharmaceutical, form, route of administration and therapeutic use.		N/A	N/A
<input type="checkbox"/> Sources for Manual Brachytherapy 12 VAC 5-481-2010	Sealed Source			
<input type="checkbox"/> Sources for Manual Brachytherapy – Ophthalmic Use Only 12 VAC 5-481-2010	Sealed Source			
<input type="checkbox"/> Sealed Sources for Diagnosis 12 VAC 5-481-2020	Sealed Source			
<input type="checkbox"/> Sealed Source(s) in a Device for Therapy – Teletherapy Unit 12 VAC 5-481-2040	Sealed Source			
<input type="checkbox"/> Sealed Source(s) in a Device for Therapy – Remote Afterloader Unit 12 VAC 5-481-2040	Sealed Source			
<input type="checkbox"/> Sealed Source(s) in a Device for Therapy – Gamma Stereotactic Radiosurgery Unit 12 VAC 5-481-2040	Sealed Source			
<input type="checkbox"/> Other Medical Use of Radioactive Material or Radiation from Radioactive Material (e.g. Emerging Technology) 12 VAC 5-481-2060	For this type of use attach a detailed description of the radioactive material and intended use			
<input type="checkbox"/> Non-medical use of	Attach a detailed description			

Note: When determining both individual radionuclide and total quantities, all materials to be possessed at any one time under the license should be included:

- materials in use or possessed,
- material used for shielding, and
- materials classified as waste awaiting disposal or held for decay-in-storage.

When requesting possession limits for materials where a source exchange is anticipated (i.e., remote afterloader), the applicant should request the maximum activity per source and total activity requested. For example a remote afterloader possession limit should be requested as “not to exceed 10 curies per source and 20 curies total”.

Item 7.2: Recordkeeping for Decommissioning and Financial Assurance

Rule: *12 VAC 5-481-1680; 12 VAC 5-481-450 C*

Criteria: All licensees are required to maintain records important to decommissioning. Licensees authorized to possess licensed material in excess of the limits specified in *12 VAC 5-481-450 C* must provide evidence of financial assurance for decommissioning.

Even if no financial assurance is required, licensees are required, under *12 VAC 5-481-450 C*, to maintain records important to decommissioning in an identified location. These records must, in part, identify all areas where licensed material is (or was) used or stored and any information relevant to spills (e.g., where contamination remains after cleanup procedures or when there is a reasonable likelihood that contaminants may have spread) and leaking sealed sources. As an alternative to the potential need for site characterizations, some licensees prefer to maintain information on surveys and leak tests on an ongoing basis and as a low-cost means of providing evidence and assurance of an appropriate decommissioning status upon the termination of licensed activities and/or release of a site for non-licensed use. Licensees must transfer the records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with *12 VAC 5-481-450 C*, or to VDH before the license is terminated.

Discussion: The requirements for financial assurance are specific to the types and quantities of radioactive material authorized on a license. Most medical use applicants and licensees do not need to take any action to comply with the financial assurance requirements because either their total inventory of licensed material does not exceed the limits in *12 VAC 5-481-450 C* or because the half-life of the unsealed radioactive material used does not exceed 120 days. Applicants requesting licensed material with a half-life in excess of 120 days should determine whether financial assurance is necessary. In addition, applicants requesting more than one radionuclide must use the sum-of-the-ratios method to determine if financial assurance is needed. See **Appendix E** for additional information.

Applications for authorization to possess and use unsealed radioactive material with a half-life exceeding 120 days must be accompanied by a decommissioning funding plan or certification of financial assurance when the trigger quantities given in *12 VAC 5-481-450 C* are exceeded. Acceptable methods of providing financial assurance include trust funds,

escrow accounts, government funds, certificates of deposit, deposits of government securities, surety bonds, letters of credit, lines of credit, insurance policies, parent company guarantees, self guarantees, external sinking funds, statements of intent, special arrangements with government entities, and standby trust funds. NRC NUREG-1757, Volume 3, 'Consolidated NMSS Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness,' dated September 2003 contains acceptable wording for each mechanism authorized by the regulation to guarantee or secure funds.

VDH will authorize sealed source possession exceeding the limits given in *12 VAC 5-481-450 C* without requiring decommissioning financial assurance, for the purpose of normal sealed source exchange, for no more than 30 days. **Table 3** shows examples of the limits for selected sealed sources.

Table 3: Minimum Sealed Source Inventory Quantity Requiring Financial Assurance

Radionuclide	Activity in GBq	Activity in Ci
cesium-137 (Cs-137)	3.7×10^6	100,000
cobalt-60 (Co-60)	3.7×10^5	10,000
strontium-90 (Sr-90)	3.7×10^4	1,000

Licenses using sealed sources authorized by **12 VAC 5-481 'Virginia Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts'** generally use licensed material in a manner that would preclude releases into the environment, would not cause the activation of adjacent materials, and would not contaminate work areas. The licensee's most recent leak test should demonstrate that there has been no leakage from the sealed sources while the sealed sources were in the licensee's possession. However, any leakage of the sealed source in excess of the regulatory limits would warrant further VDH review of decommissioning procedures on a case-by-case basis.

Response from Applicant:

Item 7.2 Recordkeeping for Decommissioning and Financial Assurance

The applicant is not required to submit proof of recordkeeping for decommissioning and financial assurance during the licensing phase. This matter will be examined during an inspection.

Reference: Copies of NRC Information Notices and NUREGs including NUREG-1757, Volume 3, 'Consolidated NMSS Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness,' dated September 2003 can be accessed at NRC's web site at: <http://www.nrc.gov>.

Item 7.3: Sealed Sources and Devices

Rule: *12 VAC 5-481-440; 12 VAC 5-481-450 A 2*

Criteria: In accordance with *12 VAC 5-481-440*, applicants must provide the manufacturer's name and model number for each requested sealed source and device (except for calibration and reference sources authorized by *12 VAC 5-481-1830*). Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by NRC or an Agreement State.

Discussion: The NRC or an Agreement State performs a safety evaluation of sealed sources and devices before authorizing a manufacturer to distribute the sources or devices to specific licensees. The safety evaluation is documented in an SSDR Certificate. 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 an SSDR Certificate or specifically approved on a license. Applicants should include all possible new sources they might use, in order to minimize the need for license amendments if they change model or vendor.

An applicant should consult with the proposed supplier or manufacturer to ensure that requested sources and devices are compatible with each other and that they conform to the SSDR designations registered with NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source-device combination that would alter the description or specifications from those indicated in the respective SSDR Certificates without obtaining VDH's prior permission in a license amendment. To ensure that sealed sources and devices are used in ways that comply with the registration certificates, applicants should obtain copies of the certificates and discuss them with the manufacturer.

In addition, many sealed sources must have a National Institute of Standards and Technology (NIST) traceable calibration prior to use. Refer to **Item 9.17** for additional information on calibration of therapy sealed sources.

Reference: Copies of NRC Information Notices and NUREGs including NUREG-1556, Vol. 3, Rev. 1, '*Consolidated Guidance about Materials Licensees: Applications for Sealed Source and Device Evaluation and Registration*,' dated April 2004 can be accessed at NRC's web site: <http://www.nrc.gov>.

Note: SSD registration certificates are also available by calling VDH at (804) 864-8150.

Item 7.4: Disposition of Material and Termination of License

Rule: *12 VAC 5-481-510; 12 VAC 5-481-450 A 2; 12 VAC 5-481-1690; 12 VAC-5-481-450 C; 12 VAC 5-481-510; 12 VAC 5-481-100; 12 VAC 5-481-500*

Criteria: Pursuant to the rule requirements described above, the licensee must do the following:

- Notify VDH, in writing, within 30 days of:
 - Decision to permanently discontinue all activities involving materials authorized under the license.
- Notify VDH, 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 *12 VAC 5-481-500*;
- Conduct decommissioning, as required by *12 VAC 5-481-450 C*; and
- Submit to VDH, a completed VDH Form 'Certificate of Disposition of Materials' and demonstrate that the premises are suitable for release for unrestricted use (e.g., results of final survey).
- Before a license is terminated, send the records important to decommissioning to VDH. If licensed activities are transferred or assigned in accordance with *12 VAC 5-481-570*, transfer records important to decommissioning to the new licensee.

Discussion: Useful guidance and other aids related to decommissioning are:

- NUREG-1757, Volume 2, 'Consolidated NMSS Decommissioning Guidance: Characterization, Survey, and Determination of Radiological Criteria,' dated September 2003, contains the current regulatory guidance concerning decommissioning of facilities and termination of licenses.
- NUREG-1757, Volume 2, includes a table (Table H.1) of acceptable license termination screening values of common beta/gamma radionuclides for building surface contamination. NUREG-1757, Volume 2, also contains methods for conducting site-specific dose assessment for facilities with contamination levels above those in the table.
- 'Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)', Revision 1, dated August 2000, should be reviewed by licensees who have large facilities to decommission. This document may be accessed at the U.S. Environmental Protection Agency's website: <http://www.epa.gov>
- An acceptable computer code for calculating screening values to demonstrate compliance with the unrestricted dose limits is D and D, Version 2.1.0, (McFadden and others, 2001).

Note: The licensee's obligations are to undertake the necessary decommissioning activities, to submit VDH Form 45007 'Certificate of Disposition of Materials' (**Appendix C**), and to perform any other actions as summarized in the 'Criteria.'

References:

- A copy of VDH Form, 'Certificate of Disposition of Materials' is located in **Appendix C** and also on the VDH website at: <http://www.vdh.virginia.gov/rad/RHP-Index.asp>
- McFadden, K., D.A. Brosseau, W.A. Beyeler, and C.D. Updegraff, 'Residual Radioactive Contamination from Decommissioning - User's Manual D and D Version 2.1,' NUREG/CR-5512, Volume 2, U.S. Nuclear Regulatory Commission, Washington, D.C., April 2001.

Item 8: Facilities and Equipment

Rule: *12 VAC 5-481-450 A 2*

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

Discussion: In *12 VAC 5-481-450 A 2*, VDH states that an application will be approved if, among other things, the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. Facility and equipment requirements depend on the scope of the applicant's operations (e.g., planned use of the material, the types of radioactive emissions, the quantity and form of radioactive materials possessed, etc.). Applicants should focus particularly on operations using large quantities of radioactive materials; preparation steps involving liquids, gases, and volatile radioactive materials; and the use of alpha-emitters, high-energy photon-emitters, and high-energy beta-emitters.

Item 8.1: Facility Diagram

Rule: *12 VAC 5-481-10; 12 VAC 5-481-630; 12 VAC 5-481-640; 12 VAC 5-481-720; 13 VAC 5-481-730; 12 VAC 5-481-780; 12 VAC 5-481-790; 12 VAC 5-481-850; 12 VAC 5-481-860; 12 VAC 5-481-990; 12 VAC 5-481-440; 12 VAC 5-481-450 A 2; 12 VAC 5-481-1680; 12 VAC 5-481-520; 12 VAC 5-481-530; 12 VAC 5-481-1690; 12 VAC 5-481-1870; 12 VAC 5-481-2010; 12 VAC 5-481-2040*

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

Discussion: Applicants must describe the proposed facilities and equipment as required by *12 VAC 5-481-440, 12 VAC 5-481-450, 12 VAC 5-481-460, 12 VAC 5-481-510, 12 VAC 5-481-520*. The facility diagram should include the room or rooms and adjacent areas where radioactive material is prepared, used, administered, and stored that is sufficient to demonstrate that the facilities and equipment are adequate to protect health and minimize danger to life or property.

For types of use permitted by *VAC 5-481-1900* and *12 VAC 5-481-1920*, applicants should provide room numbers for areas in which radioactive materials are used or prepared for use (i.e., "hot labs"). When information regarding an area or room is provided, adjacent areas and rooms, including those above and below, should be described. For types of use permitted by *12 VAC 5-481-1950* and *12 VAC 5-481-2010*, applicants should provide the above information and in addition they should provide the locations where sources are stored. Describe the rooms where patients will be housed if they cannot be released under *12 VAC 5-481-1870*. The discussion should include a description of shielding, if applicable. For types of use permitted by *12 VAC 5-481-2020*, the applicant should provide the room numbers of use.

For types of use permitted by *VAC 5-481-2040*, the applicant should provide all of the information discussed above and the shielding calculations for the facility as described for the facility as described in the diagram. When preparing applications for use under *12 VAC 5-481-2060*, applicants should review the above to determine the type of information appropriate to evaluate the adequacy of the facilities.

Licenseses are required by *12 VAC 5-481-1680* to obtain a license amendment before adding to or changing an area of use identified in the application or on the license, except for areas of use where radioactive material is used only in accordance with *12 VAC 5-481-1900 and 12 VAC 5-481-1920*.

Licenseses are required by *12 VAC 5-481-1690* to notify VDH within 30 days following changes in areas of use for *12 VAC 5-481-1900 and 12 VAC 5-481-1920* radioactive material.

Regulatory requirements, the principle of ALARA, good medical care, and access control should be considered when determining the location of the therapy patient's room or a therapy treatment room.

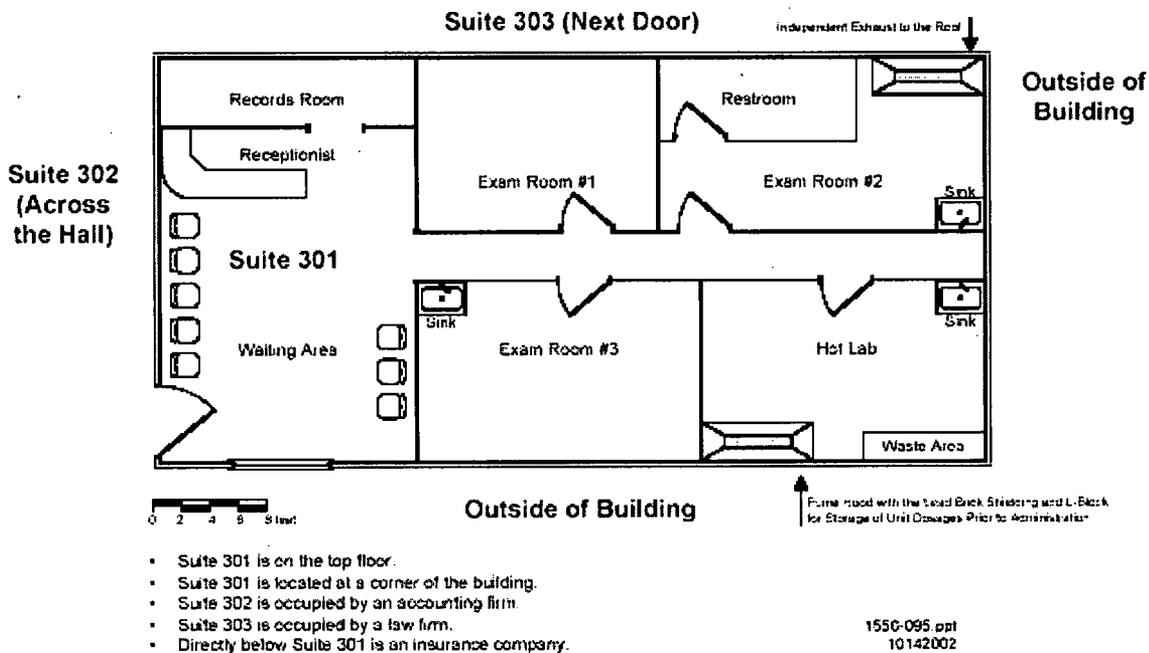


Figure 1: Facility Diagram for Nuclear Medicine Suite

The applicant should demonstrate that the limits specified in *12 VAC 5-481-720* will not be exceeded. If the calculations demonstrate that these limits cannot be met, indicate any further steps that will be taken to limit exposure to individual members of the public. The applicant may consider the following options:

- Adding shielding to the barrier in question, with corresponding modification of the facility description if necessary.
- Requesting prior VDH authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem) and demonstrating that the requirements of *VAC 5-481-720* will be met. The applicant must demonstrate the need for and the expected duration of operations that will result in an individual dose in excess of the limits specified in *12 VAC 5-481-720*. A program to assess and control dose

within the 5 mSv (0.5 rem) annual limit and procedures to be followed to maintain the dose ALARA must be developed.

Applicants who wish to perform studies with PET radiopharmaceuticals are reminded that rooms in which patients will rest (e.g., “quiet rooms”) may require additional shielding to achieve the public dose limits specified in *12 VAC 5-481-720*, particularly if more than one patient will be present at the same time.

If applicants are proposing to use portable shielding to protect health and minimize danger to life or property, they should describe the alternative equipment and administrative procedures they propose to use for evaluation and approval by VDH. If applicants elect to use portable shielding they should commit to having administrative procedures to control configuration management to maintain doses within regulatory limits.

If radiopharmaceutical therapy and brachytherapy patient rooms are added after the initial license is issued, additional room diagrams should be submitted if the room design (including shielding) and the occupancy of adjacent areas are significantly different from the original diagrams provided. A written description should be submitted for simple changes.

For teletherapy units, it may be necessary to restrict use of the unit’s primary beam if the treatment room’s walls, ceiling, or floor will not adequately shield adjacent areas from direct or scattered radiation. Electrical, mechanical, or other physical means (rather than administrative controls) must be used to limit movement or rotation of the unit (e.g., electrical or mechanical stops). Some applicants have found it helpful to have a sample response for guidance. The following is an example of an acceptable response on the use of a rotational unit with an integral beam absorber (also called a beam catcher):

- “For the primary beam directed toward the integral beam absorber, electrical or mechanical stops are set so that the primary beam must be centered (within plus or minus 2 degrees) on the integral beam absorber and, in that configuration, the attenuated primary beam may be rotated 360 degrees pointing toward the floor, east wall, ceiling, and west wall.”; and
- “For the primary beam directed away from the integral beam absorber, electrical or mechanical stops permit the unattenuated primary beam to be directed in a 95-degree arc from 5 degrees toward the west wall to vertically down toward the floor to 90 degrees toward the east wall.”

Experience has shown that, given this type of example, many applicants can make changes to accommodate their own situations (e.g., use of a vertical unit, use of a rotational unit without an integral beam absorber).

Response from Applicant:

Item 8.1 Facilities Diagram (Check box and attach requested information.)

- We will submit the information in the section titled 'Facilities Diagram' in VAREG "Guidance for Medical Use of Radioactive Material."

Note: 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 prepared, used or stored, as provided above under the heading 'Discussion';
- Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms; indicate whether the room is a restricted or unrestricted area as defined in *12 VAC 5-481-10*; and
- Provide shielding calculations and include information about the type, thickness and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy including the dimensions of any portable shield, if one is used; source storage safe, etc.).

In addition to the above, for teletherapy and GSR facilities, applicants should provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.

References: National Council on Radiation Protection and Measurements (NCRP) Report 49, '*Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies up to 10 MeV*'; Report 102, '*Medical X-Ray, Electron Beam and Gamma Ray Protection for Energies up to 50 MeV (Equipment Design, Performance and Use)*'; and Report 40, '*Protection Against Radiation from Brachytherapy Sources*' may be helpful in responding to the items above. In addition, NRC's NUREG/CR-6276, '*Quality Management in Remote Afterloading Brachytherapy*' and NRC's NUREG/CR-6324, '*Quality Assurance for Gamma Knives*' may also be helpful in responding to the items above. However please note that references to *10 CFR Part 35* in these NRC NUREGs may be outdated because NRC's rule was amended after these documents were published.

Item 8.2: Radiation Monitoring Instrumentation

Rule: *12 VAC 5-481-630; 12 VAC 5-481-990; 12 VAC 5-481-1000; 12 VAC 5-481-450 A 2; 12 VAC 5-481-1710; 12 VAC 5-481-1810; 12 VAC 5-481-2070*

Criteria: All licensees shall possess calibrated radiation detection and measuring instruments for radiation protection including:

- survey and monitoring instruments; and
- quantitative measuring instruments needed to monitor the adequacy of radioactive materials containment and contamination control.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with *12 VAC 5-481-630* must include provisions for survey instrument calibration [*12 VAC 5-481-750*]. Licensees shall possess instruments used to measure radiation levels, radioactive contamination, and radioactivity, as applicable. Instruments used for quantitative radiation measurements must be calibrated for the radiation measured. The instruments must be available for use at all times when radioactive material is in use. The licensee must possess survey instruments sufficiently sensitive to measure the type and energy of radiation used, including survey instruments used to locate low energy or low activity seeds (e.g., I-125, Pd-103) if they become dislodged in the operating room or patient's room.

Usually, it is not necessary for a licensee to possess a survey meter solely for use during sealed source diagnostic procedures, since it is not expected that a survey be performed each time such a procedure is performed. In these cases, it is acceptable for the meter to be available on short notice in the event of an accident or malfunction that could reduce the shielding of the sealed source(s). Surveys may be required to verify source integrity of the diagnostic sealed source and to ensure that dose rates in unrestricted areas and public and occupational doses are within regulatory limits.

Survey meter calibrations must be performed by persons, including licensed personnel, who are specifically authorized by VDH, NRC or another Agreement State to perform calibrations. One method a licensee may use to determine if the service is qualified to perform these activities is to determine that it has a VDH, NRC or another Agreement State license. Alternatively, an applicant may choose to develop, implement, and maintain procedures to ensure instruments are calibrated, or propose an alternative method for calibration

Appendix I provides guidance regarding appropriate instrumentation and survey instrument calibration procedures.

Response from Applicant:

ITEM 8.2 RADIATION MONITORING INSTRUMENTS (Check all that apply)

- We will identify the instrument type, sensitivity, range for each type of radiation detected and state whether the instrument will be used for 'measuring' or 'detection'. Additionally if only one survey instrument is to be used we will describe what is done when the survey instrument is being calibrated or repaired.

AND

- We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.

AND

- We will provide a description of the instrumentation (e.g. gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys or leak testing and analysis.

AND ONE OF THE FOLLOWING

- We will use radiation monitoring instruments that will be calibrated by a person authorized by VDH, the NRC or another Agreement State to perform survey meter calibrations.

OR

- We will follow survey meter calibration procedures in accordance with Appendix I of VAREG "Guidance for Medical Use of Radioactive Material."

References: Copies of NRC NUREGs including NUREG-1556, Vol. 18, 'Program-Specific Guidance About Service Provider Licenses,' dated November 2000 can be accessed at NRC's web site, <http://www.nrc.gov>.

Item 8.3: Dose Calibrator and other Equipment used to Measure Dosages of Unsealed Radioactive Material

Rule: 12 VAC 5-481-450; 12 VAC 5-481-1710; 12 VAC 5-481-1730; 12 VAC 5-481-1800; 12 VAC 5-481-1820; 12 VAC 5-481-2070

Criteria: In 12 VAC 5-481-1800 and 12 VAC 5-481-1820, VDH describes requirements for the use, possession, calibration, and check of instruments (e.g., dose calibrators) used to measure patient dosages.

Discussion: As described in 12 VAC 5-481-1820, dosage measurement is required for licensees who prepare patient dosages.

- If the licensee uses only unit dosages made by a manufacturer or preparer licensed under 12 VAC 5-481-1820, the licensee is not required to possess an instrument to measure the dosage. Furthermore, licensees who receive unit dosages of radioactive material and do not split the dosages may rely on the provider's dose label for the measurement of the dosage and decay-correct the dosage to the time of administration.
- However, pursuant to 12 VAC 5-481-1800, if the licensee performs direct measurements of dosages in accordance with 12 VAC 5-481-1820 (e.g., prepares its own dosages, breaks up unit dosages for patient administration, or decides to measure unit dosages) the licensee is required to possess and calibrate all instruments used for measuring patient dosages.

Currently, no alpha-emitting nuclides are used in unsealed form in medicine. This document does not, therefore, provide guidance on the measurement of these radionuclides. Equipment used to measure dosages must be calibrated in accordance with nationally recognized standards (e.g., ANSI) or the manufacturer's instructions. The measurement equipment may be a well ion chamber, a liquid scintillation counter, etc., as long as the instrument can be calibrated appropriately and is both accurate and reliable.

For other than unit dosages, the activity must be determined by direct measurement, by a combination of radioactivity measurement and mathematical calculation, or by a combination of volumetric measurement and mathematical calculation. However, there are inherent technical difficulties to overcome. For beta-emitting radionuclides, these difficulties include dependence on geometry, lack of an industry standard for materials used in the manufacture of vials and syringes, and lack of an NIST-traceable standard for some radionuclides used. For instance, when determining the dosage of P-32, assays with a dose calibrator may result in inaccuracies caused by inherent variations in geometry; therefore, a volumetric measurement and mathematical calculation may be more accurate. Licensees must assay patient dosages in the same type of vial and geometry as used to determine the correct dose calibrator settings. Using different vials or syringes may result in measurement errors due, for example, to the variation of bremsstrahlung created by interaction between beta particles and the differing dosage containers. Licensees are reminded that beta emitters should be shielded using a low-atomic-numbered material to minimize the production of bremsstrahlung. When a high activity source is involved, consideration should be given to adding an outer shield made from material with a high atomic number to attenuate bremsstrahlung.

Response from Applicant:

<p>Item 8.3 Dose Calibrator and Other Equipment Used To Measure Dosages of Unsealed Radioactive Material (Check all that apply)</p> <p><input type="checkbox"/> Not applicable. (Will only use unit doses or no unsealed radioactive material use)</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will identify the instrument type, manufacturer, and model number. Additionally, if only one dose calibrator is possessed, we will describe what is done when the dose calibrator is being calibrated or repaired.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.</p>
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Item 8.4: Dosimetry Equipment – Calibration and Use

Rule: 12 VAC 5-481-450 A 2; 12 VAC 5-481-1710; 12 VAC 5-481-1730; 12 VAC 5-481-2010; 12 VAC 5-481-2040; 12 VAC 5-481-2070

Criteria: The above rule references contain VDH requirements, including record-keeping requirements, for verification and periodic spot-checks of source activity or output. To perform these measurements, the applicant must possess appropriately calibrated dosimetry equipment. For sealed sources used in therapy, and in particular, for new types of use, licensees should select dosimetry equipment that will accurately measure the output or the activity of the source.

For manual brachytherapy sources and LDR remote afterloader sources licensees may use source activity or output determined by an AAPM registered manufacturer or AAPM accredited calibration laboratory. The AAPM website at: www.aapm.org maintains a listing of these manufacturers and calibration laboratories.

Discussion: Except for manual brachytherapy sources and low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer in accordance with **12 VAC 5-481 'Virginia Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts'**, the applicant must possess a calibrated dosimetry system (e.g., Farmer chamber, electrometer, well-type ionization chamber) that will be used to perform calibration measurements of sealed sources to be used for patient therapy. Dosimetry systems and/or sealed sources used to calibrate the licensee's dosimetry systems must be traceable to NIST or to a laboratory accredited by AAPM, pursuant to **12 VAC 5-481-2040**. The licensee must maintain records of calibrations for the duration of the license.

The licensee's AMP must perform full calibrations of sealed sources and devices used for therapy in accordance with published protocols accepted by nationally recognized bodies (e.g., ANSI). (**Note:** The medical physicist who performs calibrations for sources in **12 VAC 5-481-2010** need not be an authorized medical physicist except for calculating the activity of Sr-90 sources.) The licensee's AMP must calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. In addition, the licensee must perform spot-check measurements of sealed sources and devices used for therapy in accordance with written procedures established by the AMP (**12 VAC 5-481-2040**). The calibration procedures described by AAPM Task Group No. 21 and Reports 41, 46, 51, 54, 59, 61, and 67 or any published protocol approved by a nationally recognized body, as applicable, may be used. The calibration procedures should address, in part:

- The method used to determine the exposure rate (or activity) under specific criteria (i.e., distances used for the measurement, whether the measurement is an "in air" measurement or done using a phantom configuration of the chamber with respect to the source(s) and device, scatter factors used to compute the exposure rate, etc.).

Full calibrations, as described in greater detail in **Item 9.17**, must be performed before first medical use, whenever spot-check measurements (if required) indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for decay, following replacement of the sources or reinstallation of the unit in a new location not previously described in the license, following any repairs of the unit that include removal of sealed sources or major repair of the components associated with the source exposure assembly, and at intervals as defined in **12 VAC 5-481-2040**.

12 VAC 5-481-2010 requires that manual brachytherapy sources must be calibrated only initially, prior to use.

Response from Applicant:

Item 8.4 Dosimetry Equipment – Calibration and Use (Check all that apply)

**COMPLETE THIS SECTION ONLY IF REQUESTING LICENSE AUTHORIZATION FOR:
HDR, GAMMA STEREOTACTIC RADIOSURGERY UNIT, TELETHERAPY OR BRACHYTHERAPY USE**

- We will calibrate dosimetry equipment in accordance with the requirements in 12 VAC 5-481-2040.
- AND
- We have developed and will implement a written calibration procedure for a therapy sealed source that meets the requirements in 12 VAC 5-481-2010 and 12 VAC 5-481-2040 (as applicable to the type of medical use requested).
- AND
- We will identify the instrument type, manufacturer, and model number.

References: Copies of AAPM Task Group No. 21, '*A Protocol for the Determination of Absorbed Dose from High-Energy Photon and Electron Beams*', AAPM Task Group No. 40, '*Comprehensive QA for Radiation Oncology*', AAPM Report No. 54, '*Stereotactic Radiosurgery*', AAPM Task Group No. 56, '*Code of Practice for Brachytherapy Physics*', may be obtained from the American Association of Physicists in Medicine, One Physics Ellipse, College Park, MD 20740-3843 or by ordering electronically from <http://www.aapm.org>.

Item 8.5: Other Equipment and Facilities

Rule: 12 VAC 5-481-630; 12 VAC 5-481-450 A 2; 12 VAC 5-481-480; 12 VAC 5-481-490; 12 VAC 5-481-1970; 12 VAC 5-481-2010; 12 VAC 5-481-2040

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

Discussion: The applicant must describe, in **Item 8.5** of the application, other equipment and facilities available for safe use and storage of radioactive material listed in **Item 7.1** of the application (e.g., fume hoods, xenon traps, emergency response equipment, area monitors, remote handling tools, source transport containers, patient viewing and intercom systems, interlock systems). This description should be identified as an attachment.

Applicants who use PET radiopharmaceuticals should describe any additional shielding material being used (e.g., PET specific syringe shields or vial shields).

The applicant must describe additional facilities and equipment for the radiopharmaceutical therapy program to safely receive, use, store, and dispose of radioactive material. The applicant should focus on facilities to be used for radioactive drug therapy administration and patient accommodations (i.e., private room with private bath). I-131 sodium iodide is the most widely used source of radiopharmaceutical therapy. If the radionuclide is administered in volatile liquid form, it is

important to place the patient dosage in a closed environment (i.e., a fume hood). Also note there are hazards associated with volatile iodine in pill form; applicants should consider this in establishing their radiological controls. When patients are treated with I-131 sodium iodide, sources of contamination include airborne I-131, urine, perspiration, saliva, and other secretions. If release limits *12 VAC 5-481-1870* might be exceeded, provide a room with a private bath as described in **Item 8.1** of this document.

To facilitate decontamination of the patient's room, floors, toilet areas, sink areas, counter tops, and other permeable surfaces, the licensee should consider covering areas with disposable materials having plastic on one side and an absorbent material on the other. In addition, items handled by the patient may be covered with plastic. If the radiopharmaceutical administered is secreted in perspiration or saliva, or may by some other means present as a source of surface contamination, then it may be helpful to place removable covers on telephone handsets, faucet and toilet handles, television remote controls, door handles, and nurse call buttons. P-32 is effectively shielded by a plastic syringe. After P-32 has been administered to a patient, there is no external radiation hazard; therefore, isolation of patients who have administrations of P-32 is not required. P-32 administered in colloidal form can contaminate bandages and dressings; therefore, waste containers labeled for disposal of radioactive wastes should be readily available.

For teletherapy, GSR, and HDR facilities, the licensee shall require any individual entering the treatment room to ensure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels. A beam-on radiation monitor permanently mounted in each therapy treatment room that is equipped with an emergency power supply separate from the power supply for the therapy unit meets the requirements of *12 VAC 5-481-2040*. In addition, the beam-on monitors traditionally installed in therapy treatment rooms can provide a visible indication (e.g., flashing light) of an exposed or partially exposed source.

The applicant shall describe the system, required by *12 VAC 5-481-2040*, used to view and communicate with the patient continuously while the patient is in the treatment room. If a shielded viewing window will be used, the thickness, density, and type of material used shall be specified. If a closed-circuit television system (or some other electronic system) will be used to view the patient, the backup system or procedure to be used in case the electronic system malfunctions shall be specified, or the applicant must commit to suspending all treatments until the electronic system is repaired and functioning again. The communication system must allow the patient to communicate with the unit operator in the event of medical difficulties. An open microphone system is recommended to allow communication without requiring the patient to move to activate controls.

The applicant must also provide adequate equipment and controls to maintain exposures of radiation to workers ALARA and within regulatory limits. *12 VAC 5-481-2040*, in part, requires that each door leading into the treatment room be provided with an electrical interlock system to control the on-off mechanism of the therapy unit. The interlock system must cause the source(s) to be shielded if the door to the treatment room is opened when the source is exposed. The interlock system must also prevent the operator from initiating a treatment cycle unless the treatment room entrance door

is closed. Additionally, the interlock must be wired so that the source(s) cannot be exposed after interlock interruption until the treatment room door is closed and the source(s) on-off control is reset at the console.

Due to the unique characteristics of pulsed dose-rate remote afterloaders (PDR) and the lack of constant surveillance of their operation, a more sophisticated alarm system is essential to ensure the patient is protected during treatment. In addition to the above, it is necessary, under *12 VAC 5-481-840, 12 VAC 5-481-450, 12 VAC 5-481-480, 12 VAC 5-481-490, 12 VAC 5-481-570, 12 VAC 5-481-2040* to ensure the following:

- The PDR device control console is *not* accessible to unauthorized personnel during treatment;
- A primary care provider checks the patient to ensure that the patient's device has not been moved, kinked, dislodged, or disconnected;
- A more sophisticated interlock/warning system is normally installed for PDR devices. This system should perform the following functions or possess the following characteristics:
 - The signal from the PDR device and the signal from the room radiation monitor should be connected in such a manner that an audible alarm sounds if the room monitor indicates the presence of radiation and the device indicates a "safe" or retracted position;
 - The alarm circuit should also be wired in such a manner that an audible alarm is generated for any device internal error condition that could indicate the unintended extension of the source. This would constitute a circuit that generates the audible alarm when either the "source retracted and radiation present" or appropriate internal error condition(s) exist;
 - The "source safe and radiation present" signal should also be self-testing. If a "source not safe" input is received without a corresponding "radiation present" signal, the circuit should generate an interlock/warning circuit failure signal that will cause the source to retract. Reset this circuit manually before attempting to continue treatment;
 - The audible alarm should be sufficiently loud to be clearly heard by the facility's responsible device/patient monitoring staff at all times; and
 - No provisions for bypassing this alarm circuit or for permanently silencing the alarm should be made to the circuit as long as the room radiation monitor is indicating the presence of radiation. If any circuitry is provided to mute the audible alarm, such circuitry should not mute the alarm for a period of more than 1 minute. Controls that disable this alarm circuit or provide for silencing the alarm for periods in excess of 1 minute should be prohibited.

If the alarm circuit is inoperative for any reason, licensees shall prohibit further treatment of patients with the device until the circuit has been repaired and tested. If the alarm circuit fails during the course of a patient treatment, the treatment in progress may continue as long as continuous surveillance of the device is provided during each treatment cycle or fraction.

Applicants may submit information on alternatives to fixed shielding as part of their facility description. This information must demonstrate that the shielding will remain in place during the course of patient treatment.

For patient rooms where low dose-rate (LDR) remote afterloader use is planned, neither a viewing nor an intercom system is required. However, the applicant should describe how the patient and device will be monitored during treatment to ensure that the sources and catheter guide tube are not disturbed during treatment and to provide for prompt detection of any operational problems with the LDR device during treatment.

Response from Applicant:

Item 8.5 Other Equipment And Facilities (Check box and attach requested information)

- A detailed description of additional equipment and facilities available for the safe use and storage of radioactive materials requested is attached.

Note: For manual brachytherapy facilities, provide a description of the emergency response equipment. For teletherapy, GSR, and remote afterloader facilities, provide a description of the following:

- Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room;
- Area radiation monitoring equipment;
- Viewing and intercom systems (except for LDR units);
- Steps that will taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) are in the treatment room;
- Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons, and
- Emergency response equipment.

Item 9: Radiation Protection Program

Rule: *12 VAC 5-481-630; 12 VAC 5-481-990; 12 VAC 5-481-450; 12 VAC 5-481-490; 12 VAC 5-481-1700; 12 VAC 5-481-2070*

Criteria: *12 VAC 5-481-630* states that each licensee must develop, document, and implement a radiation protection program commensurate with the scope of the licensed activity. The program must be sufficient to ensure compliance with the provisions of **12 VAC 5-481 ‘Virginia Radiation Protection Regulations’, Part IV ‘Standards For Protection Against Radiation’**. The licensee is responsible for the conduct of all licensed activities and the acts and omissions of individuals handling licensed material. *12 VAC 5-481-490* provides that VDH may incorporate into radioactive material licenses, at the time of issuance or thereafter, additional requirements and conditions that it deems appropriate or necessary to, in part, protect health or to minimize danger to life and property, *12 VAC 5-481-630* describes the licensee management’s authorities and responsibilities for the radiation protection program. *12 VAC 5-481-1700* sets forth four circumstances in which the licensee may revise its radiation protection program without VDH approval.

Discussion: Licensees must abide by all applicable rules, develop, implement, and maintain procedures when required, and/or provide requested information about the proposed radiation protection program during the licensing process. The applicant should consider the following functional areas (as applicable to the type of medical program):

- Audit program;
- Occupational dose;
- Public dose;
- Minimization of contamination;
- Operating and emergency procedures;
- Material receipt and accountability;
- Ordering and receiving;
- Opening packages;
- Sealed source inventory;
- Use records;
- Leak tests;
- Area surveys;
- Procedures for administrations requiring a written directive;
- Safe use of unsealed licensed material;
- Installation, maintenance, adjustment, repair, and inspection of therapy devices containing sealed sources;
- Spill procedures;
- Emergency response for sealed sources or devices containing sealed sources;
- Release of patients or human research subjects;
- Safety procedures for therapy treatments where patients are hospitalized;
- Procedures for device calibration, safety checks, operation, and inspection;
- Mobile medical service;
- Transportation; and
- Waste management.

Item 9.1: Audit Program

Rule: *12 VAC 5-481-630; 12 VAC 5-481-990*

Criteria: Under *12 VAC 5-481-630*, licensees must annually review the content and implementation of the radiation protection program. The review should ensure the following:

- Compliance with VDH and applicable DOT regulations and the terms and conditions of the license;
- Occupational doses and doses to members of the public are ALARA (*12 VAC 5-481-630*);
- Records of audits and other reviews of radiation protection program content are maintained for 3 years after the record is made.

Discussion: The applicant should develop and implement procedures for the required audit of the radiation protection program's content and implementation. **Appendix K** contains a suggested medical licensee audit. Some sections of **Appendix K** may not apply to every licensee and may not need to be addressed during each audit. For example, licensees do not need to address areas that do not apply to their activities, and activities that have not occurred since the last audit need not be reviewed at the next audit. Audits of the radiation protection program must be conducted at intervals not to exceed 12 months.

VDH encourages licensee management to conduct performance-based audits by observing work in progress, interviewing staff about the radiation protection program, and spot-checking required records. As part of their audit programs, licensees should consider performing unannounced audits of authorized and supervised users.

It is essential that once identified, violations and radiation safety concerns are corrected comprehensively and in a timely manner. The following three-step corrective action process has proven effective:

- Conduct a complete and thorough review of the circumstances that led to the violation;
- Identify the root cause of the violation; and
- Take prompt and comprehensive corrective actions that will address the immediate concerns and prevent recurrence of the violation.

VDH will review the licensee's audit results and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. Depending on the significance of the violation, if the violation is identified by the licensee and the three corrective steps are taken, VDH may exercise discretion and may elect not to cite a violation. VDH's goal is to encourage prompt identification and prompt, comprehensive correction of violations and deficiencies.

Under *12 VAC 5-481-990*, licensees must maintain records of audits and other reviews of radiation protection program content and implementation for 3 years from the date of the record. Audit records should contain audit findings, noted deficiencies, and corrective actions.

Response from Applicant:

Item 9.1 Radiation Safety Audit Program

The applicant is not required to submit its audit program to VDH for review during the licensing phase. This matter will be examined during an inspection.

References: Copies of NRC Information Notices including: NRC's IN 96-28, '*Suggested Guidance Relating to Development and Implementation of Corrective Action*', dated May 1, 1996 can be accessed at NRC's web site, <http://www.nrc.gov>.

Item 9.2: Occupational Dose

Rule: 12 VAC 5-481-630; 12 VAC 5-481-640; 12 VAC 5-481-650; 12 VAC 5-481-670; 12 VAC 5-481-700; 12 VAC 5-481-710; 12 VAC 5-481-750; 12 VAC 5-481-760; 12 VAC 5-481-990; 12 VAC 5-481-1040; 12 VAC 5-481-1710

Criteria: Applicants must do either of the following:

- Demonstrate that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 % of the allowable limits.

OR

- Monitor external and/or internal occupational radiation exposure [12 VAC 5-481-760].

Table 4: Investigational Levels

Part of Body	Investigational Level I (mrem per year)	Investigational Level II (mrem per year)
Whole body; head; trunk including male gonads; arms above the elbow; or legs above the knee	500 (5 mSv)	1500 (15 mSv)
Hands; elbows; arms below the elbow; feet; knee; leg below the knee; or skin	5000 (50 mSv)	15,000 (150 mSv)
Lens of the eye	1500 (15 mSv)	4500 (45 mSv)

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 12 VAC 5-481-630, must include provisions for monitoring occupational dose. The licensee must evaluate the exposure of all occupational workers (e.g., nurses, technologists) to determine if monitoring is required to demonstrate compliance with 12 VAC 5-481-750. Licensees must consider the internal and external dose and the occupational workers' assigned duties when evaluating the need to monitor occupational radiation exposure. Review of dosimetry histories for workers previously engaged in similar duties may be helpful in assessing potential doses.

When evaluating external dose from xenon gas, the licensee may take credit for the reduction of dose resulting from the use of xenon traps. Additionally, periodic checks of the trap effluent may be used to ensure proper operation of the xenon trap. Licensees may vent xenon gas directly to the atmosphere as long as the effluent concentration is within 12 VAC 5-481 'Virginia Radiation Protection Regulations, Part IV 'Standards For Protection Against Radiation' limits.

When evaluating dose from aerosols, licensees may take credit for the reduction of dose resulting from the use of aerosol traps. Licensees may vent aerosols directly to the atmosphere as long as the effluent concentration is within 12 VAC 5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards For Protection Against Radiation' limits.

Appendix L provides a procedure for monitoring external occupational exposure.

If external dose monitoring is necessary, the applicant should describe the type of personnel dosimetry, such as film badges, optically stimulated luminescence dosimeters (OSL), and thermoluminescent dosimeters (TLDs), that personnel will use. If occupational workers handle licensed material, the licensee should evaluate the need to provide extremity monitors, which are required if workers are likely to receive a dose in excess of 0.05 Sv (5 rem) shallow-dose equivalent (SDE), in addition to whole-body badges. Additionally, applicants should ensure that their personnel dosimetry program contains provisions that personnel monitoring devices be worn so that the part of the body likely to receive the greatest dose will be monitored.

Some licensees use self-reading dosimeters in lieu of processed dosimetry. This is acceptable if the regulatory requirements are met. See American National Standards Institute (ANSI) N322, *Inspection and Test Specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters*, for more information. If pocket dosimeters are used to monitor personnel exposures, applicants should state the useful range of the dosimeters, along with the procedures and frequency for their calibration and maintenance as required by *12 VAC 5-481-750*.

When personnel monitoring is needed, most licensees use either OSLs or TLDs that are supplied by a processor holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP). TLDs are usually exchanged quarterly. Under *12 VAC 5-481-750*, licensees must verify that the processor is accredited by NVLAP for the type of radiation for which monitoring will be performed. Consult the NVLAP-accredited processor for its recommendations for exchange frequency and proper use.

It may be necessary to assess the intake of radioactivity for occupationally exposed individuals in accordance with *12 VAC 5-481-670* and *12 VAC 5-481-760*. If internal dose monitoring is necessary, the applicant must measure the following:

- Concentrations of radioactive material in air in work areas;
- Quantities of radionuclides in the body;
- Quantities of radionuclides excreted from the body; or
- Combinations of these measurements.

The applicant should describe in its procedures the criteria used to determine the type of bioassay and the frequencies at which bioassay (both *in vivo* and *in vitro*) will be performed to evaluate intakes. The criteria also should describe how tables of investigational levels are derived, including the methodology used by the evaluated internal dose assessments, i.e., the empirical models used to interpret the raw bioassay data. The bioassay procedures should provide for baseline, routine, emergency, and follow-up bioassays. If a commercial bioassay service will be used, the applicant must ensure that the service is licensed to perform these activities by VDH, NRC or another Agreement State.

NRC's RG 8.9, Revision 1, 'Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program' and NUREG/CR-4884, 'Interpretation of Bioassay Measurements,' outline acceptable criteria that applicants may use in developing their bioassay programs.

NRC Regulatory Issue Summary (RIS) 2002-06, "Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays," provides guidance for evaluating occupational dose when some exposure is due to X-rays and dosimeters are used to measure exposure behind lead aprons and elsewhere.

Note: The definition of "shallow-dose equivalent" in 12 VAC 5-481-10 changes the area for averaging dose to skin from 1 square centimeter to 10 square centimeters (see NRC Regulatory Issue Summary 2002-10, "Revision of the Skin Dose Limit in 10 CFR Part 20").

12 VAC 5-481-650 describes the requirements for summing external and internal doses. Applicants must ensure that their occupational monitoring procedures include criteria for summing external and internal doses.

Response from Applicant:

Item 9.2 Occupational Dose (Check all that apply)

We will provide a description of facilities and equipment used for monitoring occupational exposure. (Description is Attached)

AND ONE OF THE FOLLOWING

We will follow the procedures in Appendix L of VAREG "Guidance for Medical Use of Radioactive Material" for monitoring occupational dose.

OR

We have developed and will implement written procedures for monitoring occupational dose in accordance with 12 VAC 5-481-630 and that meet the requirements in 12 VAC 5-481 'Virginia Radiation Protection Regulations, Part IV 'Standards For Protection Against Radiation' (Procedures are attached)

References:

- National Institute of Standards and Technology (NIST) Publication 810, 'National Voluntary Laboratory Accreditation Program Directory,' is published annually and is available for purchase from the Government Printing Office and on the Internet at <http://ts.nist.gov/ts/htdocs/210/214/scopes/programs.htm>.
- Copies of ANSI N322 may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018, or ordered electronically from <http://www.ansi.org>.
- NUREG/CR-4884, 'Interpretation of Bioassay Measurements' and NRC Regulatory Guide 8.9, Revision 1, 'Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program' can be accessed at NRC's web site, <http://www.nrc.gov>.
- NRC Regulatory Issue Summary 2002-06, 'Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays' can be accessed at NRC's web site, <http://www.nrc.gov>.

- NRC Regulatory Issue Summary 2002-10, 'Revision of the Skin Dose Limit in 10 CFR Part 20' can be accessed at NRC's web site, <http://www.nrc.gov>.

Item 9.3: Public Dose

Rule: *12 VAC 5-481-720; 12 VAC 5-481-730; 12 VAC 5-481-840; 12 VAC 5-481-1050*

Criteria: Licensees must do the following:

- Ensure that licensed material will be used, transported, and stored in such a way that members of the public will not receive more than 1 mSv (100 mrem) in one year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour from licensed operations;
- Ensure air emissions of radioactive materials 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 these emissions; and
- Control and maintain constant surveillance of licensed material that is not in storage and secure stored licensed material from unauthorized access, removal, or use.

Discussion: Members of the public include persons who are not radiation workers. This includes workers who work or may be near locations where licensed material is used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where it is used or stored. Public dose is controlled, in part, by ensuring that licensed material is secure (e.g., located in a locked area) to prevent unauthorized access or use by individuals coming into the area. Some medical use devices containing licensed material are usually restricted by controlling access to the keys needed to operate the devices and/or to keys to the locked storage area. Only AUs and personnel using radioactive material under their supervision should have access to these keys.

The definition of "public dose" in *12 VAC 5-481-10* does not include doses received due to exposure to patients released in accordance with *12 VAC 5-481-1870*. Dose to members of the public in waiting rooms was addressed in the NRC Information Notice (IN) 94-09. The provisions of *12 VAC 5-481-720* should not be applied to radiation received by a member of the general public from patients released under *12 VAC 5-481-1870*. If a patient is released pursuant to *12 VAC 5-481-1870*, licensees are not required to limit the radiation dose to members of the public (e.g., visitor in a waiting room) from a patient to 0.02 mSv (2 mrem) in any one hour. Patient waiting rooms need only be controlled for those patients not meeting the release criteria in *12 VAC 5-481-1870*.

12 VAC 5-481-720 allows licensees to permit visitors to a patient who cannot be released under *12 VAC 5-481-1870* to receive a dose greater than 1 mSv (0.1 rem) provided the dose does not exceed 5 mSv (0.5 rem) and the authorized user has determined before the visit that it is appropriate. NRC Regulatory Issue Summary 2005-24 'Control of Radiation Dose to Visitors of Hospital Patients' provides guidance to licensees on methods that may be used to estimate and control radiation doses to visitors of hospitalized patients who have been administered radioactive material.

The licensee must control emissions of radioactive material to air such that the individual member of the public likely to receive the highest total effective dose equivalent (TEDE) does not exceed the constraint level of 0.10 mSv (10 mrem) per year from those emissions. If exceeded, the licensee must report this in accordance with *12 VAC 5-481-1110*, and take prompt actions to ensure against recurrence.

Public dose is also affected by the choice of storage and use locations and conditions. Licensed material may produce a radiation field and must be located so that the public dose in an unrestricted area (e.g., an office or the exterior surface of an outside wall) does not exceed 1 mSv (100 mrem) in a year or 0.02 mSv (2 mrem) in any one hour. Licensees should use the concepts of time, distance, and shielding when choosing storage and use locations. Decreasing the time, increasing the distance, and using shielding (i.e., brick, concrete, lead, or other solid walls) will reduce the radiation exposure.

Licensees can determine the radiation levels adjacent to licensed material either by direct measurement, calculations or a combination of direct measurements and calculations using some or all of the following:

- typical known radiation levels provided by the manufacturer;
- the “inverse square” law to evaluate the effect of distance on radiation levels;
- occupancy factor to account for the actual presence of the member of the public; and
- limits on the use of licensed material.

If, after making an initial evaluation, a licensee changes the conditions used for the evaluation (e.g., the location of licensed material within a designated room, the type or frequency of licensed material use, or the occupancy of adjacent areas), the licensee must perform a new evaluation to ensure that the public dose limits are not exceeded and take corrective action, as needed.

Response from Applicant:

Item 9.3 Public Dose

No response is required, in this license application, however the licensee's evaluation of public dose will be examined during an inspection.

Item 9.4: Minimization of Contamination

Rule: *12 VAC 5-481-450 A 2; 12 VAC 5-481-1840*

Criteria: Applicants for new licenses must describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

Discussion: All applicants for new licenses need to consider the importance of designing and operating their facilities to minimize the amount of radioactive contamination generated at the site during its operating lifetime and to minimize the generation of radioactive waste during decontamination. This is especially important for licensed activities involving unsealed radioactive material. As described in **Item 9.14, 'Spill Procedures,'** cleanup procedures should be implemented for contamination events. Recommended limits for acceptable levels of surface contamination in restricted and unrestricted areas are provided in **Appendix R, Tables 13 and 14.**

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

Response from Applicant:

<p>Item 9.4 Minimization Of Contamination (Check one box)</p> <p><input type="checkbox"/> We will follow the cleanup procedures from Appendix R, Tables 9 and 10, of VAREG "Guidance for Medical Use of Radioactive Material" to minimize the amount of radioactive contamination and radioactive waste generated at our facility.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will develop, implement and maintain procedures to minimize the amount of radioactive contamination and radioactive waste generated at our facility. (Procedures are attached.)</p>
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Item 9.5: Operating and Emergency Procedures

Rule: 12 VAC 5-481-2260; 12 VAC 5-481-630; 12 VAC 5-481-780; 12 VAC 5-481-790; 12 VAC 5-481-840; 12 VAC 5-481-900; 12 VAC 5-481-990; 12 VAC 5-481-1090; 12 VAC 5-481-490; 12 VAC 5-481-1100; 12 VAC 5-481-1710; 12 VAC 5-481-1730; 12 VAC 5-481-1870; 12 VAC 5-481-1960; 12 VAC 5-481-1970; 12 VAC 5-481-2010; 12 VAC 5-481-2040; 12 VAC 5-481-2080

Criteria: This section summarizes operating and emergency procedures. Many of these procedures are covered in greater detail in other sections of this document.

The licensee shall develop, implement, and maintain specific operating and emergency procedures containing the following elements:

- Instructions for opening packages containing licensed material;

- Using licensed material, operating therapy treatment devices, and performing routine maintenance on devices containing sealed sources, according to the manufacturer's written recommendations and instructions and in accordance with regulatory requirements;
- Instructions for conducting area radiation level and contamination surveys;
- Instructions for administering licensed material in accordance with the WD;
- Steps to take, and whom to contact (e.g., RSO, local officials), when the following has occurred: (a) leaking or damaged source, (b) device malfunction and/or damage, (c) licensed material spills, (d) theft or loss of licensed material, (e) releases of xenon-133, or (f) any other incidents involving licensed material;
- Steps for source retrieval and access control of damaged sealed source(s) and/or malfunctioning devices containing sealed source(s);
- Steps to ensure that patient release is in accordance with *12 VAC 5-481-1870*;
- Steps to take if a therapy patient undergoes emergency surgery or dies;
- Instructions for calibration of survey and dosage measuring instruments;
- Periodic spot checks of therapy device units, sources, and treatment facilities; and
- Instructions for radioactive waste management.

AND

The licensee should consider the following:

- Provide a current copy of the operating procedures at each location of use (or, if this is not practicable, post a notice describing the procedures and stating where they may be examined).
- When developing the procedures described above, the licensee is reminded that *12 VAC 5-481-630* requires that the licensee use, to the extent practical, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA.
- In addition, when receiving and using radioactive material, the licensee is reminded that it must be licensed to possess the radioactive material and that the radioactive material must be secured (or controlled) and accounted for at all times.

Discussion: Applicants shall develop, document, and implement specific procedures as part of a radiation protection program (e.g., operating and emergency procedures) based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA. These procedures must be specific to the type and form of the licensed material used.

Sealed sources and radiopharmaceuticals used for therapy can deliver significant doses in a short time. *12 VAC 5-481-780*, *12 VAC 5-481-790*, and *12 VAC 5-481-840* describe access control to high and very high radiation areas and the security of licensed material. Unauthorized access to licensed material by untrained individuals could lead to a significant radiological hazard. Therefore, operating procedures will also need to address access control. Many licensees achieve

access control by permitting only trained individuals to have access to licensed material (e.g., keys, lock combinations, security badges). Accountability of licensed material may be ensured by conducting physical inventories, controlling receipt and disposal, and maintaining use records.

If a therapy patient undergoes emergency surgery or dies, it is necessary to ensure the safety of others attending the patient. As long as the patient's body remains unopened, the radiation received by anyone near it is due almost entirely to gamma rays. The change in emphasis when an operation or autopsy is to be performed is due to the possible exposure of the hands and face to relatively intense beta radiation. Procedures for emergency surgery or autopsy can be found in Section 5.3 of NCRP Report No. 37, *'Precautions In The Management of Patients Who Have Received Therapeutic Amounts of Radionuclides'*. **Appendix N** also provides procedures for responding to emergency surgery or death of a therapy patient.

Applicants must develop emergency procedures that address a spectrum of incidents (e.g., major spills, leaking source, medical events, interlock failure, stuck source, etc.).

After its occurrence becomes known to the licensee, VDH must be notified when licensed material in excess of 10 times the quantity specified in **12 VAC 5-481-3750** is lost or stolen. The RSO must be proactive in evaluating whether VDH notification is required for any incident involving licensed material. Refer to the rule references [**12 VAC 5-481-1090**, **12 VAC 5-481-1100**, and **12 VAC 5-481-2080**] for a description of when notifications are required.

Response from Applicant:

Item 9.5 Operating And Emergency Procedures

No response is required in this license application, however the licensee's operating and emergency procedures will be examined during an inspection.

Reference: Copies of NCRP Report No. 37, *"Precautions In The Management of Patients Who Have Received Therapeutic Amounts of Radionuclides,"* NCRP Report No. 105, *"Radiation Protection for Medical and Allied Health Personnel,"* 1989, and NCRP Report No. 107, *"Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel,"* 1990, may be obtained from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 800, Bethesda, MD 20814-3095, or ordered electronically at <http://www.ncrp.com>.

Item 9.6: Material Receipt and Accountability

Rule: **12 VAC 5-481-840; 12 VAC 5-481-900; 12 VAC 5-481-1090; 12 VAC 5-481-490; 12 VAC 5-481-570; 12 VAC 5-481-100; 12 VAC 5-481-1710; 12 VAC 5-481-1840; 12 VAC 5-481-2070**

Criteria: To maintain accountability of licensed material, licensees must do the following:

- Secure licensed material;
- Maintain records of receipt, transfer, and disposal of licensed material; and
- Conduct physical inventories at required frequencies to account for licensed material.

Discussion: Licensed materials must be tracked from “cradle to grave” to ensure accountability, to identify when licensed material could be lost, stolen, or misplaced, and to ensure that possession limits listed on the license are not exceeded. Licensees exercise control over licensed material accountability by including the following items (as applicable) in their radiation protection program:

- Physical inventories of sealed sources at intervals not to exceed 6 months;
- Ordering and receiving licensed material;
- Package opening; and
- Use records.

Response from Applicant:

<p>Item 9.6 Material Receipt And Accountability (Check one box)</p> <p><input type="checkbox"/> Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will submit a description of the frequency and procedures for ensuring that no radioactive material has been lost, stolen or misplaced (Procedures are attached).</p>

Item 9.7: Ordering and Receiving

Rule: *12 VAC 5-481-840; 12 VAC 5-481-900; 12 VAC 5-481-490; 12 VAC 5-481-100; ~~12 VAC 5-481-100~~*

Criteria: *12 VAC 5-481-900* contains the requirements for receiving packages containing licensed material. Additionally, the security of licensed material, required by *12 VAC 5-481-840*, must be considered for all receiving areas. *12 VAC 5-481-100* requires licensees, in part, to maintain records showing the receipt of radioactive material.

Discussion: Licensees must ensure that the type and quantity of licensed material possessed is in accordance with the license. Additionally, licensees must ensure that packages are secured and radiation exposure from packages is minimized.

Appendix O contains procedures for ordering and receiving licensed material.

Response from Applicant:

Item 9.7 Ordering And Receiving (Check one box)

We will develop, implement and maintain ordering and receiving procedures that will meet the criteria in the section titled "Ordering and Receiving" of VAREG "Guidance for Medical Use of Radioactive Material." (Procedures are attached)

OR

We will follow procedures for ordering and receiving in accordance with Appendix O of VAREG "Guidance for Medical Use of Radioactive Material."

Item 9.8: Opening Packages

Rule: *12 VAC 5-481-900; 12 VAC 5-481-1000*

Criteria: Licensees must ensure that packages are opened safely and that the requirements of *12 VAC 5-481-900* are met. Licensees must retain records of package surveys in accordance with *12 VAC 5-481-1000*.

Discussion: Licensees must establish, maintain, and retain written procedures for safely opening packages to ensure that the monitoring requirements of *12 VAC 5-481-900* are met and that radiation exposure to personnel coming near or in contact with the packages containing radioactive material are ALARA. **Appendix P** contains model procedures for safely opening packages containing radioactive materials. Applicants are reminded that *12 VAC 5-481-900* requires, in part, that licensees monitor the external surfaces of a labeled package for radioactive contamination within 3 hours of receipt if it is received during normal working hours, or not later than 3 hours from the beginning of the next working day, if it is received after working hours.

Response from Applicant:

Item 9.8 Opening Packages

No response is required, in this license application, however the licensee's package opening procedure will be examined during an inspection.

Item 9.9: Leak Tests

Rule: *12 VAC 5-481-740; 12 VAC 5-481-1150; 12 VAC 5-481-750; 12 VAC 5-481-1010; 12 VAC 5-481-180; 12 VAC 5-481-1840; 12 VAC 5-481-2070; 12 VAC 5-481-2080*

Criteria: VDH requires testing to determine if there is any radioactive leakage from sealed sources. Records of test results must be maintained for 3 years.

Discussion: Licensees must perform leak testing of any sealed source or brachytherapy source in accordance with *12 VAC 5-481-1840*. **Appendix Q** provides leak-testing procedures. If the licensee chooses to perform their own leak tests, provide a description of the instrumentation that will be used to perform leak tests in **Item 8.2 'Radiation Monitoring Instruments'** of the application form. *12 VAC 5-481-1840* requires licensees to perform leak tests at six-month intervals or at other intervals approved by VDH, NRC or another Agreement State and specified in the SSDR certificate and before first use unless accompanied by a certificate indicating that the test was performed within the past 6 months. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 μ Ci) of radioactivity on the sample. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking.

The leak test may be performed in-house or by a service provider authorized by VDH, NRC or another Agreement State to perform leak tests as a service to other licensees.

The licensee does not need to leak test sources if:

- Sources contain only radioactive material with a half-life of less than 30 days;
- Sources contain only radioactive material as a gas;
- Sources contain 3.7 MBq (100 μ Ci) or less of beta-emitting or gamma-emitting material, or 0.37 MBq (10 μ Ci) or less of alpha-emitting material; or
- Sources contain Ir-192 seeds in nylon ribbon.

Sources that are stored and not being used must be leak tested at least every five years [*12 VAC 5-481-740*]. The licensee, shall, however, test each such source for leakage before any use or transfer unless it has been leak-tested within 6 months before the date of use or transfer.

Response from Applicant:

Item 9.9 Leak Test (Check one box)

- Leak tests will be performed by an organization authorized by VDH, the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test kit supplied by an organization licensed by VDH, the NRC or another Agreement State to provide leak test kits to other licensees according to kit suppliers' instructions.

List the name and license number of organization authorized to perform or analyze leak test (Specify whether VDH, NRC, or other Agreement State):

Organization Name _____ License Number _____

Note: An alternate organization may be used to perform or analyze leak tests, without amending the license, provided the organization is specifically authorized by VDH, NRC or another Agreement State.

OR

- We will perform our own leak testing and sample analysis. We will follow the procedures in Appendix Q of VAREG "Guidance for Medical Use of Radioactive Material."

OR

- We will submit alternative procedures. (Procedures are attached)

References: Copies of NRC NUREGs including: NUREG-1556, Vol. 18, 'Program-Specific Guidance About Service Provider Licenses,' dated November 2000 can be accessed at NRC's web site, <http://www.nrc.gov>.

Item 9.10: Area Surveys

Rule: *12 VAC 5-481-10; 12 VAC 5-481-630; 12 VAC 5-481-640; 12 VAC 5-481-720; 12 VAC 5-481-730; 12 VAC 5-481-750; 12 VAC 5-481-990; 12 VAC 5-481-1000; 12 VAC 5-481-1050; 12 VAC 5-481-1710; 12 VAC 5-481-1860; 12 VAC 5-481-2070*

Criteria: Licensees are required to make surveys of potential radiological hazards in their workplace. For example, licensees must perform surveys to:

- 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 mSv (100 mrem) in one year and that the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour from licensed operations;
- Ensure that radioactive material will be used, transported, and stored in such a way that occupational doses to individuals will not exceed the limits specified in *12 VAC 5-481-640*;
- Control and maintain constant surveillance over radioactive material that is not in storage and secure radioactive material from unauthorized access or removal; and
- Ensure that licensed material will be used, transported, and stored in such a way that the air emissions do not exceed the constraint value in *12 VAC 5-481-630*.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with *12 VAC 5-481-630* must include provisions for area surveys. Surveys are evaluations of radiological conditions and potential hazards. These evaluations may be measurements (e.g., radiation levels measured with survey

instrument or results of wipe tests for contamination), calculations, or a combination of measurements and calculations. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess radiological conditions.

Radiation surveys are used to detect and evaluate contamination of:

- Facilities (restricted and unrestricted areas);
- Equipment;
- Incoming and outgoing radioactive packages; and
- Personnel (during use, transfer, or disposal of licensed material).

Licensees also may use surveys to plan work in areas where radioactive material or radiation exists and to evaluate doses to workers and individual members of the public.

Surveys are required when it is reasonable under the circumstances to evaluate a radiological hazard and when necessary for the licensee to comply with the appropriate rule sites. Licensees may need to perform many different types of surveys due to the particular use of radioactive materials. The most important types of surveys are as follows:

- 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 radiopharmaceuticals are handled or processed in unsealed form and where operations could cause workers to inhale radioactive material (e.g., radioiodine) or where radioactive material is or could be released to unrestricted areas;
- Bioassays to determine the kinds, quantities, or concentrations, and in some cases, the location of radioactive material in the human body. Radioiodine uptake in a worker's thyroid gland is commonly measured by external counting using a specialized thyroid detection probe;
- Surveys of external radiation exposure levels in both restricted and unrestricted areas; and
- Surveys of radiopharmaceutical packages entering (e.g., from suppliers) and departing (e.g., returned radiopharmaceuticals to the supplier).

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 workers and the public from external and internal exposure. Also, the frequency of the survey depends on the type of survey. **Appendix R** contains procedures with suggested survey frequencies for ambient radiation level and contamination surveys. For example, licensees are required to perform daily surveys in all areas where a written directive (WD) is required for preparation and administration of radiopharmaceuticals (i.e., diagnostic activities exceeding 30 μCi of I-131 and all therapy treatments); when the licensee administers radiopharmaceuticals requiring a WD in a patient's room, the licensee is not required to perform a survey if the patient is not released. However, the licensee should perform adequate surveys of patients' rooms after patient release and prior to release of the room for unrestricted use. Licensees should be cognizant of the requirement to perform surveys to demonstrate the public limits are not exceeded.

Because therapy sealed sources (including applicators and catheters) may become dislodged during implantation or after surgery, and inadvertently lost or removed, the following surveys shall be performed:

- Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted; and
- Immediately after removing the last temporary implant source from a patient or human research subject, the license shall make a survey of the patient or human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

In addition, licensees should also consider surveying the following:

- The therapy patient's bed linens before removing them from the patient's room;
- The operating room and the patient's room after source implantation (e.g., radiation level and/or visual check);
- All trash exiting the patient's room; and
- Areas of public access in and around the patient's room.

The licensee must also perform surveys to ensure that radiation levels around a patient's room after source implantation are within the regulatory requirements (e.g., less than 0.02 mSv (2 mrem) in any one hour in any unrestricted area).

Not all instruments can measure a given type of radiation (e.g., alpha, beta, and gamma). The presence of other radiation may interfere with a detector's ability to measure the radiation of interest. The energy of the radiation may not be high enough to penetrate some detector windows and be counted. The correct selection, calibration, and use of radiation detection instruments are important aspects of any radiation safety program. Additionally, applicants are reminded that probe movement speeds and surface-to-probe distances greatly affect ambient exposure rate survey results.

Response from Applicant:

Item 9.10 Area Surveys (Check one box)

We will develop, implement and maintain procedures for area surveys that will meet the criteria in the section titled 'Area Surveys' in VAREG "Guidance for Medical Use of Radioactive Material." (Procedures are attached)

OR

We will follow the procedures for area survey published in Appendix R of VAREG "Guidance for Medical Use of Radioactive Material."

Item 9.11: Procedures for Administration of Radioactive Material Requiring a Written Directive

Rule: 12 VAC 5-481-1710; 12 VAC 5-481-1720; 12 VAC 5-481-1730; 12 VAC 5-481-2070

Criteria: *12 VAC 5-481-1720* sets forth the requirements for WDs. *12 VAC 5-481-1730* requires medical use licensees to develop, maintain, and implement written procedures to provide high confidence that licensed material is administered as directed by authorized users.

Discussion: The procedures do not need to be submitted to VDH. This gives licensees the flexibility to revise the procedures to enhance effectiveness without obtaining VDH approval. **Appendix S** provides guidance on developing the procedures.

Response from Applicant:

<p>Item 9.11 Procedures For Administration of Radioactive Material Requiring A Written Directive (Check one box)</p> <p><input type="checkbox"/> We will develop, maintain and implement procedures for administration of radioactive material requiring a written directive that will meet the criteria in the section titled 'Procedures for Administrations Requiring a Written Directive' in VAREG "Guidance for Medical Use of Radioactive Material."</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> Not Applicable.</p>

Item 9.12: Safe Use of Unsealed Licensed Material

Rule: *12 VAC 5-481-630; 12 VAC 5-481-720; 12 VAC 5-481-730; 12 VAC 5-481-990; 12 VAC 5-481-1000; 12 VAC 5-481-450 A 2; 12 VAC 5-481-1710; 12 VAC 5-481-1850; 12 VAC 5-481-1860; 12 VAC 5-481-1960*

Criteria: Before using radioactive material, the licensee must develop and implement a radiation protection program that includes safe use of unsealed radioactive material.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with *12 VAC 5-481-630* must include provisions for safe use of radioactive material. Licensees are responsible for developing, documenting, and implementing procedures to ensure the security and safe use of all radioactive material from the time it arrives at their facilities until it is used, transferred, and/or disposed. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use radioactive material without undue hazard to themselves, other workers, or members of the public.

In addition, licensees must develop, implement, and maintain procedures for protective measures to be taken by occupational workers to maintain their doses ALARA. Protective measures may include:

- Use of syringe shields and/or vial shields;
- Wearing laboratory coats and gloves when handling unsealed radioactive material; and

- Monitoring hands after handling unsealed radioactive material.

Appendix T contains procedures for safe use of unsealed radioactive material.

Response from Applicant:

Item 9.12 Safe Use of Unsealed Radioactive Material (Check one box)	
<input type="checkbox"/>	We will develop, implement and maintain procedures for the safe use of unsealed radioactive material, that will meet the criteria in the section titled 'Safe Use of Unsealed Radioactive Material' in VAREG "Guidance for Medical Use of Radioactive Material." (Procedures are Attached)
	OR
<input type="checkbox"/>	We will follow the procedures for the safe use of unsealed radioactive material in Appendix T of VAREG "Guidance for Medical Use of Radioactive Material."
	OR
<input type="checkbox"/>	Not Applicable.

Item 9.13: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources

Rule: 12 VAC 5-481-630; 12 VAC 5-481-440; 12 VAC 5-481-490; 12 VAC 5-481-2040; 12 VAC 5-481-2070

Criteria: In accordance with 12 VAC 5-481-2040, licensees must ensure that therapy devices containing sealed sources are installed, maintained, adjusted, repaired, and inspected by persons specifically licensed to conduct these activities. The above activities should be conducted according to the manufacturers' written recommendations and instructions and according to the SSDR. In addition, 12 VAC 5-481-2040 requires that teletherapy and GSR units be fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to ensure that the source exposure mechanism functions properly. Maintenance is necessary to ensure that the device functions as designed and source integrity is not compromised.

Discussion: Maintenance and repair includes installation, replacement, and relocation or removal of the sealed source(s) or therapy unit that contains a sealed source(s). Maintenance and repair also includes any adjustment involving any mechanism on the therapy device, treatment console, or interlocks that could expose the source(s), reduce the shielding around the source(s), affect the source drive controls, or compromise the radiation safety of the unit or the source(s).

VDH requires that maintenance and repair (as defined above) be performed only by persons specifically licensed by VDH, NRC or an Agreement State to perform such services. Most licensee employees do not perform maintenance and repair because they do not have the specialized equipment and technical expertise to perform these activities. Applicants requesting authorization to possess and use LDR remote afterloaders should review 12 VAC 5-481-2040 before

responding to this item. *12 VAC 5-481-2040* allows for an AMP to perform certain service activities with regard to LDR remote afterloader units.

Response from Applicant:

<p>Item 9.13 Maintenance of Therapy Devices Containing Sealed Sources (Check all that apply)</p> <p><input type="checkbox"/> Not Applicable. (No therapy devices containing sealed sources)</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will contract with personnel who are licensed by VDH, the NRC or another Agreement State to perform maintenance and repair services on the specific therapy device(s) possessed by the licensee.</p> <p style="text-align: center;">OR THE FOLLOWING THREE CONDITIONS MUST BE MET</p> <p><input type="checkbox"/> We will name the proposed employee or employees and types of maintenance and repair requested.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> We will provide a description of the training and experience demonstrating that the proposed employee or employees is/are qualified by training and experience for the use requested.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> We will provide a copy of the manufacturer's training certification and an outline of the training.</p>

Note: For applicants wishing to perform in-house maintenance and repair of therapy devices, the applicant shall specify only those installation, maintenance, inspection, adjustment, and repair functions described in a certificate or letter from the manufacturer of the device that documents the employee's training in the requested function(s).

Item 9.14: Spill Procedures

Rule: *12 VAC 5-481-2260; 12 VAC 5-481-630; 12 VAC 5-481-450 A 2; 12 VAC 5-481-990; 12 VAC 5-481-1100; 12 VAC 5-481-1110; 12 VAC 5-481-490; 12 VAC 5-481-570; 12 VAC 5-481-1100; 12 VAC 5-481-670; 12 VAC 5-481-100; 12 VAC 5-481-1710*

Criteria: Before using radioactive material, the licensee must develop, document, and implement a radiation protection program that includes proper response to spills of radioactive material.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with *12 VAC 5-481-630* must include provisions for responding to spills or other contamination events in order to prevent the spread of radioactive material. **Appendix N** contains emergency response procedures, including spill procedures. Spill procedures should address all types and forms of radioactive material used (e.g. unsealed and gases) and should be posted in restricted areas where radioactive materials are used or stored. The instructions should specifically state the names and telephone numbers of persons to be notified (e.g., RSO, staff, state and local authorities, and VDH,

when applicable). Additionally, the instructions should contain procedures for evacuation of the area, containment of spills and other releases, appropriate methods for re-entering, and for decontaminating facilities (when necessary).

Response from Applicant:

<p>Item 9.14 Spill Procedures (Check one box)</p> <p><input type="checkbox"/> We will develop, implement and maintain procedures for response to spills of radioactive material. (Procedures are attached.)</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will follow procedures for response to spills of radioactive material in accordance with Appendix N of VAREG "Guidance for Medical Use of Radioactive Material".</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> Not Applicable. (Unsealed radioactive material not used)</p>

Note: The Department of Health Radioactive Materials Program office number is (804) 864-8150 during regular business hours (7:45 a.m. to 4:30 p.m.). For spills requiring immediate notification after normal business hours, use VDEM's 24 hour emergency telephone number: 1-800-468-8892. Identify the emergency as radiological.

The names and telephone numbers of the person to be notified of a spill or contamination event do not need to be included in the submitted Spill Procedures. However these names and telephone numbers should be included in the posted spill procedures at your facility.

Item 9.15: Emergency Response for Sealed Sources or Devices Containing Sealed Sources

Rule: 12 VAC 5-481-2260; 12 VAC 5-481-630; 12 VAC 5-481-990; 12 VAC 5-481-1090; 12 VAC 5-481-1100; 12 VAC 5-481-1110; 12 VAC 5-481-490; 12 VAC 5-481-100; 12 VAC 5-481-1710; 12 VAC 5-481-2010; 12 VAC 5-481-2040; 12 VAC 5-481-2070; 12 VAC 5-481-450

Criteria: Before handling sealed sources or using devices containing sealed sources, the applicant must develop, document, and implement written procedures for emergency response. VDH requires that written procedures shall be developed, implemented, and maintained for responding to an abnormal situation involving manual brachytherapy, a remote afterloader unit, a teletherapy unit, or a gamma stereotactic radiosurgery unit. The procedures must be submitted to VDH with your application and should include as appropriate:

- Steps to take if brachytherapy seeds are lost in an operating room;
- Steps to take if a brachytherapy seed is breached;
- Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

- The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
- The names and telephone numbers of AUs, AMPs, and the RSO to be contacted if the unit or console operates abnormally.

For *12 VAC 5-481-2040* modalities, a copy of these procedures must be physically located at the therapy unit console. The instructions must inform the operator of procedures to be followed if the operator is unable to place the source(s) in the shielded position, or remove the patient from the radiation field with controls from outside the treatment room.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with *12 VAC 5-481-630* must include provisions for responding to incidents involving sealed sources or devices containing sealed sources. Emergency procedures must address all types of radioactive material and devices used and should be posted in restricted areas where sealed sources are used or stored. The instructions must specifically state the names and telephone numbers of persons to be notified (e.g., RSO, staff, state and local authorities, and VDH, when applicable). Additionally, the instructions must contain procedures for evacuation and security of the involved area(s), source recovery, area re-entry, and decontamination of facilities (when necessary). All equipment necessary for complying with emergency procedures shall be available near each treatment room; for example, these may include remote handling tools, t-bars, Allen keys, and shielded containers.

The applicant must establish and follow written procedures for emergencies that may occur (e.g., a manual brachytherapy source becomes dislodged, a therapy source fails to retract or return to the shielded position, or a GSR couch fails to retract). A copy of the manufacturer's recommendations and instructions should be given to each individual performing therapy treatments or operating the therapy device. Practice drills, using nonradioactive (dummy) sources (when possible), must be practiced annually or more frequently, as needed. The drills should include dry runs of emergency procedures that cover stuck or dislodged sources and applicators (if applicable), and emergency procedures for removing the patient from the radiation field. Team practice may also be important for adequate emergency coordination for such maneuvers as removing a patient from a malfunctioning GSR unit and manual movement of the patient treatment table. These procedures, designed to minimize radiation exposure to patients, workers, and the general public should address the following points, as applicable to the type of medical use:

- When the procedures are to be implemented, such as any circumstance in which the source becomes dislodged, cannot be retracted to a fully shielded position, or the patient cannot be removed from the beam of radiation.
- The actions specified for emergency source recovery or shielding that primarily consider minimizing exposure to the patient and health care personnel while maximizing safety of the patient.
- Process for identifying and decontaminating equipment if a brachytherapy source ruptures.
- The step-by-step actions for single or multiple failures that specify the individual(s) responsible for implementing the actions. The procedures should clearly specify which steps are to be taken under different

scenarios. The procedure should specify situations in which surgical intervention may be necessary and the steps that should be taken in that event.

- Location of emergency source recovery equipment and specification of what equipment may be necessary for various scenarios. Emergency equipment should include shielded storage containers, remote handling tools, and if appropriate, supplies necessary to surgically remove applicators or sources from the patient and tools necessary for removal of the patient from the device.
- Giving first consideration to minimizing exposure to the patient, usually by removing the patient from the room (rather than using tools to attempt to return the source to the off position). *Note: If the first step of the emergency procedures for therapy units specifies pressing the emergency bar on the therapy unit console, the applicant is advised that this action may cause the source to return to the off position but may also cut power to the entire therapy unit or to the gantry or the couch.*
- Instructing the staff to act quickly and calmly, and to avoid the primary beam of radiation or areas contaminated with radioactive material.
- Specifying who is to be notified.
- Requirements to restrict access to (lock, as necessary) and post the treatment area with appropriate warning signs as soon as the patient and staff are out of the treatment room.

Model procedures for responding to manual brachytherapy emergencies are provided in **Appendix J**.

Response from Applicant

Item 9.15 Emergency Response for Sealed Sources or Devices Containing Sealed Sources (Check one box)

We will develop, implement and maintain procedures for emergency response for sealed sources or devices containing sealed sources. (Procedures are attached)

OR

Not Applicable (Brachytherapy sources, high activity sealed sources or devices containing sealed sources not used)

Item 9.16: Release of Patients or Human Research Subjects

Rule: 12 VAC 5-481-1710; 12 VAC 5-481-1870; 12 VAC 5-481-2070

Criteria: Licensees may release from confinement patients or human research subjects (patients) who have been administered radioactive material if the TEDE to any other individual from exposure to the released patient is not likely to exceed 5 mSv (0.5 rem). Licensees must provide radiation safety instructions to patients released (or their parent or guardian) in accordance with 12 VAC 5-481-1870.

Discussion: *12 VAC 5-481-1870* requires that the licensee provide the released individual (patient) with instructions, including written instructions, on actions recommended to maintain doses to other individuals ALARA if the TEDE to any other individual is likely to exceed 1 mSv (0.1 rem). If the dose to a breast-feeding infant or a child could exceed 1 mSv (0.1 rem), assuming there was no interruption of breast-feeding, the instructions also shall include:

- Guidance on the interruption or discontinuation of breast-feeding; and
- Information on the potential consequences of failure to follow the guidance. This implies that the licensee will confirm whether a patient is breast-feeding before releasing the patient.

In addition, *12 VAC 5-481-1870* and *12 VAC 5-481-2070* require that the licensee maintain a record of the basis for authorizing the release of an individual for 3 years after the release date, if the TEDE is calculated by:

- Using the retained activity rather than the activity administered;
- Using an occupancy factor less than 0.25 at 1 meter;
- Using the biological or effective half-life; or
- Considering the shielding by tissue.

In *12 VAC 5-481-1870* and *12 VAC 5-481-2070*, the licensee is required to maintain a record for 3 years after the date of release that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a TEDE exceeding 5 mSv (0.5 rem).

Appendix U provides guidance to the applicant for determining when:

- The licensee may authorize the release of a patient who has been administered radiopharmaceuticals or who has been treated with implants containing radioactive material (**Section U.1 of Appendix U**), and
- Instructions to the patient are required by *12 VAC 5-481-1870* (**Section U.2 of Appendix U**).

Guidance on recordkeeping requirements in *12 VAC 5-481-1870* and *12 VAC 5-481-2070* is contained in **Section U.3 of Appendix U**. The appendix lists activities for commonly used radionuclides and the corresponding dose rates with which a patient may be released in compliance with the dose limits in *12 VAC 5-481-1870*.

Response from Applicant:

Item 9.16 Release of Patients or Human Research Subjects (Check one box)

We will develop, implement and maintain procedures for release of patients or human research subjects that will meet the criteria in the section titled 'Release of Patients or Human Research Subjects' in VAREG "Guidance for Medical Use of Radioactive Material." (Procedures are attached)

OR

We will follow the procedures for release of patients or human research subjects in Appendix U of VAREG "Guidance for Medical Uses of Radioactive Material."

OR

Not applicable. (Studies only performed under *12 VAC 5-481-1900* & *12 VAC 5-481-1920*)

Item 9.17: Mobile Medical Service

Rule: *12 VAC 5-481-630; 12 VAC 5-481-570; 12 VAC 5-481-100; 12 VAC 5-481-10; 12 VAC 5-481-1680; 12 VAC 5-481-1880; 12 VAC 5-481-2040; 12 VAC 5-481-2070; 12 VAC 5-481-2980; 12 VAC 5-481-3000; 12 VAC 5-481-3020; 12 VAC 5-481-3030; 12 VAC 5-481-590; 49 CFR Parts 171-178*

Criteria: In addition to the requirements in *12 VAC 5-481-1880*, mobile medical service licensees must comply with all other applicable regulations.

Discussion: Applicants for licensure of mobile medical services should review this guide for information to be submitted as part of their applications; many of the requirements in these sections are relevant to use of radioactive material by mobile medical service providers with details being dependent upon the scope of such programs. “Temporary job site” means a location, other than specific location(s) of use authorized on the license, where mobile medical services are conducted. Mobile medical service licensees may transport licensed material and equipment into a client’s building, or may bring patients into the mobile coach/van. In either case, the coach/van should be located on the client’s property that is under the client’s control.

Self-contained mobile medical service involves a mobile treatment or administration facility that provides ready-to-deliver mobile medical services on arrival at a client’s site. Companies providing transportation only will not be licensed for medical use under **12 VAC 5-481 ‘Virginia Radiation Protection Regulations’, Part VII ‘Use of Radionuclides in the Healing Arts’**. Before using a remote afterloader for this type of service, the device should be installed in an appropriately shielded treatment room.

The general types of services provided as mobile medical services are:

- Mobile medical services (radioactive material, trained personnel, and facility) that provide the device/facility (e.g., in-coach/van use) and treatment of (or administration to) patients at the client site. These mobile medical service providers are responsible for all aspects of radioactive material use and authorized patient treatments (or administrations); and
- Mobile medical service providers (radioactive material and trained personnel) that provide the transportation to and use of the radioactive material within the client’s facility. These mobile medical service providers are also responsible for all aspects of radioactive material use and authorized patient treatments (or administrations).

Mobile medical service licensees must ensure that the criteria in *12 VAC 5-481-1870* are met before releasing patients in their facilities.

Refer to **Appendix V** for additional guidance on information to provide in applications.

Response from Applicant:

Item 9.17 Mobile Medical Service (Check one box)

We will provide the information requested, along with any procedures mentioned in Appendix V of VAREG "Guidance for Medical Use of Radioactive Material." (Procedures are attached)

OR

Not applicable.

Note: NRC licensees and Agreement State licensees that request reciprocity for activities conducted in the Commonwealth of Virginia are subject to the general license provisions described in *12 VAC 5-481-590*. This general license authorizes persons holding a specific license from the NRC or an Agreement State to conduct the same activity in the Commonwealth of Virginia if the specific license issued by the NRC or an Agreement State does not limit the authorized activity to specific locations or installations.

Item 9.18: Transportation

Rule: *12 VAC 5-481-630; 12 VAC 5-481-570; 12 VAC 5-481-100; 12 VAC 5-481-2980; 12 VAC 5-481-2970; 12 VAC 5-481-3000; 12 VAC 5-481-3020; 12 VAC 5-481-3030; 49 CFR Parts 171-178*

Criteria: Applicants who will prepare for shipment, ship, or transport radioactive materials, including radioactive waste, must develop, implement, and maintain safety programs for the transport of radioactive material to ensure compliance with DHFS and DOT regulations.

Discussion: Most packages of radioactive material for medical use contain quantities of radioactive material that require use of Type A packages. Additionally, many packages shipped by medical licensees (e.g., unused radiopharmaceutical dosages) frequently meet the "Limited Quantity" criteria described in *49 CFR 173.421* and are therefore exempted from certain DOT requirements, provided certain other less restrictive requirements are met (e.g., activity in the package is less than the limited quantity and the radiation level on the surface of the package does not exceed 0.005 mSv per hour (0.5 mrem per hour)).

The general license in *12 VAC 5-481-3000*, 'General license: NRC-approved package,' provides the authorization used by most licensees to transport, or to deliver to a carrier for transport, radioactive material in a package for which a license, certificate of compliance, or other approval has been issued by NRC. This general license is subject to certain conditions. *12 VAC 5-481-2980* sets forth the requirements for transportation of radioactive material. *12 VAC 5-481-2970* exempts any physician licensed by a state to dispense drugs in the practice of medicine, who is also licensed under *12 VAC 5-481*

‘Virginia Radiation Protection Regulations’, Part VII ‘Use of Radionuclides in the Healing Arts’, or the equivalent NRC or Agreement State regulations from the requirements in *12 VAC 5-481-2980*. This exemption applies to transport by the physician of radioactive material for use in the practice of medicine.

Some medical use licensees (e.g., teletherapy or gamma stereotactic radiosurgery) may need to ship licensed material in Type B packages. *12 VAC 5-481-3000*, *12 VAC 5-481-3020* and *12 VAC 5-481-3030* sets forth the Type B package requirements for transporting or delivering the package to a carrier for transport. These include registration as a user of the package and having a VDH-approved quality assurance (QA) plan. For information about these QA plans, see the NRC’s Revision 1 of RG 7.10, *‘Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material,’* dated June 1986. To obtain this document contact NRC Region I at 1-800-432-1156 or visit the NRC’s web site located at www.nrc.gov. For further information about registering as a user of a package or submitting a QA program for review, contact NRC’s Spent Fuel Project Office by calling NRC toll-free at (800) 368-5642, extension 415-8500. For information about associated fees, contact NRC’s OCFO by calling NRC toll-free at (800) 368-5642, extension 415-7544.

Most medical use licensees that ship radioactive material have chosen to transfer possession of radioactive materials to a manufacturer (or service licensee) with a VDH, NRC or another Agreement State license, who then acts as the shipper. The manufacturer (or service licensee), who is subject to the provisions of *12 VAC 5-481-3000* or *12 VAC 5-481-3030*, as appropriate, then becomes responsible for proper packaging of the radioactive materials and compliance with VDH and DOT regulations. Licensees who do this must ensure that the manufacturer (or service licensee):

- Is authorized to possess the radioactive material at temporary job sites (e.g., the licensee’s facilities); and
- Actually takes possession of the radioactive material under its license.

Additionally, for Type B package shipments, the licensee should verify and the manufacturer (or service licensee) must:

- Use an approved Type B package;
- Register with NRC as a user of the Type B package;
- Possess a VDH approved QA plan; and
- Be authorized to possess the material at temporary job sites (e.g., the licensee’s facilities).

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

During an inspection, VDH uses the provisions of *12 VAC 5-481-2980* to examine and enforce various DOT requirements applicable to medical use licensees. **Appendix W** lists major DOT regulations that apply to medical licensees.

Response from Applicant:

Item 9.19 Transportation

No response is needed during the license process; this issue will be reviewed during inspection.

NOTE: Before offering a Type B package for shipment, a licensee needs to have registered as a user of the package and obtained the department's approval of its QA Program. Alternatively, the licensee may choose to transfer possession of radioactive material to an irradiator manufacturer (or distributor) (or service licensee) with a VDH, NRC or another agreement state license whom then acts as the shipper.

Note: No response is needed from applicants during the licensing phase. However, before making shipments of radioactive materials on its own in a Type B package, a licensee must have registered with NRC as a user of the package and obtained VDH's concurrence. Transportation issues will be reviewed during inspection.

References: 'A Review of Department of Transportation Regulations for Transportation of Radioactive Materials' can be obtained by calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4425.

Item 9.19: Sealed Source Inventory

Rule: *12 VAC 5-481-840; 12 VAC 5-481-100; 12 VAC 5-481-1840; 12 VAC 5-481-2010; 12 VAC 5-481-2070*

Criteria: VDH requires the licensee in possession of a sealed source or brachytherapy source to conduct a semi-annual physical inventory of all such sources in its possession. Inventory records must be maintained for 3 years.

Discussion: According to *12 VAC 5-481-1840*, the licensee must conduct a semi-annual physical inventory of all sealed sources and brachytherapy sources in its possession. Individual GSR sources are exempt from this physical inventory requirement, as stated in *12 VAC 5-481-1840*. However, the licensee must maintain records of GSR source receipt, transfer, and disposal, under *12 VAC 5-481-100*, to indicate the current inventory of sources at the licensee's facility. The licensee shall retain each inventory record in accordance with *12 VAC 5-481-2070*. In addition, *12 VAC 5-481-2010* and *12 VAC 5-481-2070* require the licensee to make a record of brachytherapy source accountability when removing and returning brachytherapy sources from the storage location.

Response from Applicant:

Item 9.20 Sealed Source Inventory

No response is needed during the license process; this issue will be reviewed during inspection.

Item 9.20: Records of Dosages and Use of Brachytherapy Sources

Rule: *12 VAC 5-481-100; 12 VAC 5-481-2070*

Criteria: Licensees must record the use of licensed material to reflect proper use and accountability. Records of use must be maintained for 3 years.

Discussion: Licensees are required to make and maintain records of each dosage activity prior to medical use. The records must include:

- Radiopharmaceutical;
- Patient's or human research subject's name or identification number (if one has been assigned);
- Prescribed dosage, determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μ Ci);
- Date and time of dosage determination; and
- Name of the individual who determined the dosage.

Dosage determination for unit dosages may be made either by direct measurement or by a decay correction based on the determination (e.g., measurement) made by the manufacturer or preparer licensed under *12 VAC 5-481-470 J* or equivalent NRC or Agreement State requirements.

If molybdenum concentration is measured under *12 VAC 5-481-2070*, records of molybdenum concentration must be made and must include, for each measured elution of technetium-99m:

- Ratio of the measurements expressed as kBq (μ Ci) of molybdenum-99 per MBq (mCi) of technetium-99m;
- Date and time of the measurement; and
- Name of the individual who made the measurement.

If the licensee uses manual brachytherapy sources, the following records of use must be kept:

- When temporary implant brachytherapy sources are removed from storage, a record will include the number and activity of sources removed, the time and date they were removed from storage, the location of use, and the name of the individual who removed them from storage;
- When temporary implant brachytherapy sources are returned to storage, a record will include the number and activity of sources returned, the time and date they were returned to storage, and the name of the individual who returned them to storage; and
- For permanent implants, a record will be made and will include the number and activity of sources removed from storage, the date they were removed from storage, the name of the individual who removed them from storage, the number and activity of sources not implanted, the date they were returned to storage, the name of

the individual who returned them to storage, and the number and activity of sources permanently implanted in the patient or human research subject.

Response from Applicant:

Item 9.21 Records of Dosages and Use of Brachytherapy Source

No response is needed during the license process; this issue will be reviewed during inspection.

Item 9.21: Safety Procedures for Treatments Where Patients are Hospitalized

Rule: *12 VAC 5-481-630; 12 VAC 5-481-750; 12 VAC 5-481-840; 12 VAC 5-481-1000; 12 VAC 5-481-1970; 12 VAC 5-481-2010; 12 VAC 5-481-2040; 12 VAC 5-481-2070*

Criteria: Applicants must develop and implement procedures to ensure that access to therapy treatment rooms, and exposure rates from therapy treatments, are limited to maintain doses to occupational workers and members of the public ALARA.

Discussion: *12 VAC 5-481-1970, 12 VAC 5-481-2010, and 12 VAC 5-481-2040* require the licensee to take certain safety precautions regarding radiopharmaceutical therapy, manual brachytherapy, or remote afterloader brachytherapy involving patients hospitalized in accordance with *12 VAC 5-481-1870*. This section does not include teletherapy or GSR outpatient treatments. The precautions described below are to ensure compliance with the exposure limits in **12 VAC 5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards For Protection Against Radiation'**.

12 VAC 5-481-2010, and 12 VAC 5-481-2040 require licensees to perform a radiation survey of the patient (and the remote afterloader unit) immediately after removing the last temporary implant source from the patient and prior to releasing the patient from licensee control. This is done to confirm that all sources have been removed and accounted for. A record of the patient survey must be maintained for 3 years. *12 VAC 5-481-2040* requires that when sources are placed within the patient's body, licensed activities be limited to treatments that allow for expeditious removal of a decoupled or jammed source.

In addition, applicants must take the following steps for patients who cannot be released under *12 VAC 5-481-1870*:

- Provide a private room with a private sanitary facility for patients treated with a radiopharmaceutical therapy dosage (*Note: 12 VAC 5-481-1970* allows for a room shared with another radiopharmaceutical therapy patient);
- Provide a private room for patients implanted with brachytherapy sources (*Note: 12 VAC 5-481-2010* allows for a room shared with another brachytherapy patient);

- Visibly post a ‘*Radioactive Materials*’ sign on the patient’s door and note on the door or in the patient’s chart stating where and how long visitors may stay in the patient’s room [12 VAC 5-481-1970 and 12 VAC 5-481-2010];
- Either monitor material and items removed from the patient’s room (e.g., patient linens, surgical dressings) with a radiation detection survey instrument set on its most sensitive scale with no interposed shielding to determine that their radioactivity cannot be distinguished from the natural background radiation level or to confirm that they do not contain brachytherapy sources, or handle them as radioactive waste [12 VAC 5-481-1970 and 12 VAC 5-481-750]; and
- Notify the RSO, or his/her designee, and AU as soon as possible if the patient has a medical emergency or dies [12 VAC 5-481-1970, 12 VAC 5-481-2010, and 12 VAC 5-481-2040].

12 VAC 5-481-750 requires licensees to perform adequate surveys to evaluate the extent of radiation levels. Therefore, licensees must evaluate the exposure rates around patients who are hospitalized in accordance with 12 VAC 5-481-1870 following the dosage administration or implant (e.g., measured exposure rates, combination of measured and calculated exposure rates).

12 VAC 5-481-840 requires licensees to secure radioactive material in storage from unauthorized access or removal. Therefore, licensees must ensure that access to rooms where patients are hospitalized, in accordance with 12 VAC 5-481-1870, is limited to authorized personnel. Access control and appropriate training of authorized personnel may prevent unauthorized removal of radioactive material and unnecessary personnel exposures.

In order to control exposures to individuals in accordance with 12 VAC 5-481 ‘**Virginia Radiation Protection Regulations**’, Part IV ‘**Standards For Protection Against Radiation**’, the licensee should consider briefing patients on radiation safety procedures for confinement to bed, visitor control, identification of potential problems, notification of medical staff in the event of problems, and other items as applicable and consistent with good medical care.

Response from Applicant:

Item 9.21 Safety Procedures For Treatments Where Patients Are Hospitalized

No response is needed during the license process; this issue will be reviewed during inspection.

Note: NRC Regulatory Issue Summary 2005-24 ‘*Control of Radiation Dose to Visitors of Hospital Patients*’ provides guidance to licensees on methods that may be used to estimate and control radiation doses to visitors of hospitalized patients who have been administered radioactive material.

Item 9.22: Recordkeeping

Rule: *12 VAC 5-481-910; 12 VAC 5-481-100; 12 VAC 5-481-2070*

Criteria: Licensees must maintain records as provided in *12 VAC 5-481-910; 12 VAC 5-481-100; 12 VAC 5-481-2070*.

Discussion: The licensee must maintain certain records to comply with **12 VAC 5-481 ‘Virginia Radiation Protection Regulations’**, the conditions of the license, and commitments made in the license application and correspondence with VDH. Operating procedures should identify which individuals in the organization are responsible for maintaining which records.

A table of recordkeeping requirements appears in **Appendix Y**.

Response from applicant:

Item 9.22 Recordkeeping

No response is needed during the license process; this issue will be reviewed during inspection.

Item 9.23: Reporting

Rule: *12 VAC 5-481-1090; 12 VAC 5-481-1100; 12 VAC 5-481-2080*

Criteria: Licensees are required to report to VDH via telephone, written report, or both in the event that the safety or security of radioactive material may be compromised. The specific events that require reporting are explained in *12 VAC 5-481-2080, 12 VAC 5-481-1090*, and in *12 VAC 5-481-1100*. The timing and type of report are specified within these parts.

Discussion: VDH requires licensees to report incidents that might compromise the health and safety of patients, health care providers, or the public. Therefore **12 VAC 5-481 ‘Virginia Radiation Protection Regulations’, Part III ‘Licensing of Radioactive Material’, Part IV ‘Standards for Protection Against Radiation’ and Part VII ‘Use of Radionuclides in the Healing Arts’** include provisions that describe reporting requirements associated with the medical use of radioactive material.

A table of reporting requirements appears in **Appendix Z**.

Response from Applicant:

Item 9.22 Reporting

No response is needed during the license process; this issue will be reviewed during inspection.

Item 10: Waste Management

Rule: *12 VAC 5-481-630; 12 VAC 5-481-720; 12 VAC 5-481-750; 12 VAC 5-481-880; 12 VAC 5-481-910; 12 VAC 5-481-920; 12 VAC 5-481-930; 12 VAC 5-481-940; 12 VAC 5-481-950; 12 VAC 5-481-960; 12 VAC 5-481-970; 12 VAC 5-481-980; 12 VAC 5-481-990; 12 VAC 5-481-1050; 12 VAC 5-481-1060; 12 VAC 5-481-1100; 12 VAC 5-481-450 A 2; 12 VAC 5-481-570; 12 VAC 5-481-100; 12 VAC 5-481-430 G; 12 VAC 5-481-1710; 12 VAC 5-481-1890; 12 VAC 5-481-2070; 12 VAC 5-481-2980*

Criteria: Radioactive materials must be disposed of in accordance with VDH requirements by:

- Transfer to an authorized recipient;
- Decay-in-storage;
- Release in effluents within the limits in *12 VAC 5-481-720*; or
- As authorized under *12 VAC 5-481-920* through *12 VAC 5-481-950*.

Appropriate records must be maintained.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with *12 VAC 5-481-630* must include provisions for waste disposal of radioactive material. **Appendix X** contains procedures for decay-in-storage and generator or other radioactive material return to authorized recipients. *12 VAC 5-481-910* requires that licensees dispose of radioactive material only by means specified therein. For radioactive material transferred to a land disposal facility, the licensee must comply with the specific requirements in *12 VAC 5-481-960*. Applicants are reminded to take into account the following information when they develop procedures (as applicable):

- Except for material suitable for decay-in-storage and some animal carcasses handled by the licensee, solids are transferred to an authorized recipient licensed to receive such waste in accordance with *12 VAC 5-481-910*, *12 VAC 5-481-960* or in *12 VAC 5-481 'Virginia Radiation Protection Regulations'*. Follow the packaging instructions received from the transfer agent and the burial site operator. Keep the consignment sheet from the transfer agent as the record of disposal.
- When setting up a program for decay-in-storage, consider short-term and long-term storage. Long-term storage should be designed to allow for segregation of wastes with different half-lives (e.g., the use of multiple shielded containers). Containers should have shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location.

- Waste from *in vitro* kits (except mock iodine-125) that are generally licensed under *12 VAC 5-481-430 G* is exempt from waste disposal requirements in **12 VAC 5-481 ‘Virginia Radiation Protection Regulations’, Part IV ‘Standards for Protection Against Radiation’,** as set forth in *12VAC 5-481-430 G*. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.
- Consider the monitoring and control mechanisms in place to ensure compliance with the appropriate requirements regarding the release of material into air and water under *12 VAC 5-481-730* and *VAC 5-481-930*, respectively.
 - Requirements for disposal in the sanitary sewer appear in *12 VAC 5-481-930*. Material must be readily soluble or dispersible in the water. There are also monthly and annual limits, based on the total sanitary sewerage release of the facility. (Excreta from patients undergoing medical diagnosis or therapy are not subject to these limitations; see *12 VAC 5-481-930*). Make a record of the disposal in accordance with *12 VAC 5-481-1060*.
 - Limits on permissible concentrations in effluents to unrestricted areas are enumerated in **Table II of 12 VAC 5-481-3690**. These limits apply at the boundary of the restricted area. Make a record of the release in accordance with *12 VAC 5-481-1000* and *12 VAC 5-481-1050*.
 - Liquid scintillation-counting media containing up to 1.85 kBq (0.05 µCi) of H-3, I-125 or C-14 per gram of medium used may be disposed of without regard to its radioactivity (*12 VAC 5-481-950*). Make a record of the disposal in accordance with *12 VAC 5-481-1060*.
- If applicants propose to treat or dispose of radioactive material by incineration, they must receive specific approval from VDH. Contact VDH for guidance on treatment or disposal of material by incineration in accordance with *12 VAC 5-481-940*.
- Applicants that wish to use waste volume reduction operations (e.g., compactors) must provide a detailed description (as outlined below), along with their response to **Item 8.1 ‘Facilities Diagram’**:
 - A description of the compactor to demonstrate that it is designed to safely compact the waste generated (e.g., manufacturer’s specifications; annotated sketches, photographs);
 - The types, quantities, and concentrations of the waste to be compacted;
 - An analysis of the potential for airborne release of radioactive material during compaction activities;
 - The location of the compactors in the waste processing area(s), as well as a description of the ventilation and filtering systems used in conjunction with the compactors, and procedures for monitoring filter blockage and exchange;
 - Methods used to monitor worker breathing zones and/or exhaust systems;
 - The types and frequencies of surveys that will be performed for contamination control in the compactor area;
 - The instructions provided to compactor operators, including instructions for protective clothing, checks for proper functioning of equipment, method of handling uncompacted waste, and examining containers for defects.

General Guidance for Waste Disposal

Under *12 VAC 5-481-880* and *12 VAC 5-481-1890*, all radioactivity labels must be removed or obliterated from empty or adequately decayed containers and packages prior to disposal as non-radioactive waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed. In accordance with *12VAC 5-481-1890*, radiation labels do not require removal or obliteration if the label is on materials that are within containers that will be managed as biomedical waste after they have been released from the licensee.

Remind employees that non-radioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste. Occasionally licensees should monitor all practices to limit waste generation. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.

Licensees are cautioned that, on several occasions, incinerator and sanitary landfill operators have returned waste shipments that have triggered their portal monitors. NRC Information Notice 99-33, *'Management of Wastes Contaminated with Radioactive Materials'* describes this issue in greater detail. In many cases, the waste is from patients who have been released under *12 VAC 5-481-1870*. Licensees should review state and local ordinances for disposal of waste at these facilities to ensure that their waste is acceptable.

VDH requires that licensees who transport radioactive material (including radioactive waste) outside the site of usage where transport is on public highways, or who deliver it for transport, comply with the applicable regulations of DOT in *49 CFR Parts 170 through 189*.

In all cases, consider the impact of various available disposal routes, including occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and expense.

Decay-In-Storage

For radionuclides of radioactive material with a half-life of less than 120 days, licensees may dispose of waste in ordinary trash as long as the following criteria are followed:

- Hold radioactive material for decay until the waste cannot be distinguished from background level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding;
- Remove or obliterate all radiation labels, except as noted above; and
- Maintain proper records.

Returning Sources

Because of the nature of the material contained in brachytherapy, teletherapy, and GSR sources, the only option for disposal is transfer to an authorized recipient as specified in *12 VAC 5-481-910*. Authorized recipients are the original manufacturer of the sealed source, a waste broker licensed by VDH, NRC or another Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the radioactive material (i.e., their license specifically authorizes possession of the same radionuclide, form, and use).

Medical licensees are often the first to come into contact with plutonium-powered pacemakers or the first to be contacted by nursing homes and funeral homes when a patient implanted with a pacemaker dies. If the pacemaker was not originally implanted by your facility, you should contact the hospital where the pacemaker was implanted to arrange for explanation and notify VDH. The licensee (e.g., the implanting hospital) is responsible for the follow-up, explanation, and return of the pacemaker to the manufacturer for proper disposal. NRC Information Notice 98-12, *'Licensees Responsibilities Regarding Reporting and Follow-up Requirements for Nuclear-Powered Pacemakers.'*

Before transferring radioactive material, a licensee must verify that the recipient is authorized to receive the material using one of the methods described in *12 VAC 5-481-560*. Records of the transfer must be maintained as required by *12 VAC 5-481-1100*.

Licensees should promptly dispose of unused sealed sources to minimize potential problems such as access by unauthorized individuals, use for inappropriate purposes, and improper disposal.

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.

Response from Applicant:

Item 10 Waste Management (Check all that apply)

- We will follow the waste procedures published in Appendix X of VAREG "Guidance for Medical Use of Radioactive Material."
AND / OR
- We will use: Decay-In-Storage, or Disposal of Liquids Into Sanitary Sewerage waste procedures that are published in Appendix X of VAREG "Guidance for Medical Use of Radioactive Material."
AND / OR
- We will provide procedures for waste collection, storage and disposal by any of the authorized methods described in Item 10 'Waste Management' of VAREG "Guidance for Medical Use of Radioactive Material." We will contact VDH for guidance to obtain approval of any method(s) of waste disposal other than those discussed in Item 10 'Waste Management' of VAREG "Guidance for Medical Use of Radioactive Material."

Note: NRC INs can be accessed at the NRC website: www.nrc.gov in the 'electronic reading room'.

Item 11: License Fees

On VDH Form 'Application for Radioactive Material for Medical Use', enter the fee category and the amount for a new application.

Response from Applicant:

Item 11 License Fees (Refer To Commonwealth of Virginia Administration Code 12 VAC 5-490)	
Category:	License Fee Enclosed (For new applications) <input type="checkbox"/> Yes <input type="checkbox"/> No Amount Enclosed \$ _____

Item 12: Certification

Individuals acting in a private capacity are required to sign and date VDH Form 'Application for Radioactive Material for Medical Use'. Otherwise, senior representatives of the corporation or legal entity filing the application should sign and date VDH Form 'Application for Radioactive Material for Medical Use'. **Representatives signing an application must be authorized to make binding commitments and sign official documents on behalf of the applicant.** As discussed previously in 'Management Responsibility,' signing the application acknowledges management's commitment and responsibilities for the radiation protection program. The department **will return all unsigned applications for proper signature.**

Response from Applicant:

Item 12	
I hereby certify that this application was prepared in conformance with 12 VAC 5-481 'Virginia Radiation Protection Regulations' and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.	
SIGNATURE - Applicant Or Authorized Individual	Date signed
Print Name and Title of above signatory	

Note:

- It is a violation of **12 VAC 5-481 'Virginia Radiation Protection Regulations'**, to make a willful false statement or representation on applications or correspondence.
- When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

Appendix A
VDH Form
***'Application for Radioactive Material License
for Medical Use'***

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE FOR MEDICAL USE

The Commonwealth of Virginia Department of Health (VDH) is requesting disclosure of all information on this application for the purpose of obtaining a radioactive material license. Failure to provide any information may result in denial or delay of a radioactive material license.

Instructions: Complete all items if this is an initial application or an application for renewal of a license. Refer to VAREG "Guidance for Medical Use of Radioactive Material." Use supplementary sheets where necessary. Retain one copy and submit original of the entire application to Virginia Department of Health, Radioactive Materials Program 109 Governor Street, Room 730, Richmond, VA 23218

APPLICATION TYPE

Item 1. Type Of Application (Check one box)

New License Renewal License Number _____

CONTACT INFORMATION

Item 2. Name and Mailing Address of Applicant

Item 3. Person to contact regarding this application

Applicant's Telephone Number (Include Area Code)

()

Contact's Telephone Number (Include Area Code)

()

LOCATION OF RADIOACTIVE MATERIAL

Item 4. Address(es) Where Radioactive Material Will Be Used Or Possessed (Do not use P.O. Box)

Address

Telephone Number (Include area code)

()

Is radioactive material used at other off-site locations?

Yes No

If yes, please attach an additional sheet(s) with the address(es) and a list of activities to be conducted at each location of use.

INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY

Item 5.1 Radiation Safety Officer (RSO) (Check all that apply and attach evidence of training and experience)

- We will provide the name of the proposed RSO and other potential designees who will be responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures. We will provide documentation showing delegation of authority to the Radiation Safety Officer.

Name: _____ Telephone Number (Include Area Code) (_____) _____

AND ONE OF THE FOLLOWING

- We will provide the previous license number (if issued by VDH) or a copy of the license (if issued by the NRC or an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO.

OR

- We will provide a copy of the certification(s) for the board(s) approved by VDH and as applicable to the types of use for which he or she has RSO responsibility.

AND

We will provide a written attestation, signed by a preceptor RSO, that the above training and experience as specified in 12 VAC 5-481-1750 has been satisfactorily completed and that the individual has achieved a level of radiation safety knowledge sufficient to independently function as a RSO. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.

OR

- We will provide a description of the training and experience specified in 12 VAC 5-481-1750 demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.

AND

We will provide a written attestation, signed by a preceptor RSO, that the above training and experience as specified in 12 VAC 5-481-1750 has been satisfactorily completed and that the individual has achieved a level of radiation safety knowledge sufficient to independently function as a RSO. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.

AND, IF APPLICABLE

- We will provide a description of recent related continuing education and experience as required by 12 VAC 5-481-1790.
-

Item 5.2 Authorized Users (AU) (Check all that apply and attach evidence of training and experience)

- We will attach a list of each proposed authorized user with the types and quantities of licensed material to be used.

AND ONE OF THE FOLLOWING FOR EACH AU

- We will provide the previous license number (if issued by VDH) or a copy of the license (if issued by the NRC or an Agreement State) on which the physician was specifically named as an AU for the uses requested.

OR

- We will provide a copy of the certification(s) for the board(s) approved by VDH and as applicable to the use requested.

AND

We will provide a written attestation, signed by a preceptor AU, that the training and experience as specified in 12 VAC 5-481-1910; 12 VAC 5-481-1940; 12 VAC 5-481-1980; 12 VAC 5-481-2010; 12 VAC 5-481-2040, as applicable, has been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized user. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.

OR

- We will provide a description of the training and experience as specified in 12 VAC 5-481-1910; 12 VAC 5-481-1940; 12 VAC 5-481-1980; 12 VAC 5-481-2010; 12 VAC 5-481-2030; 12 VAC 5-481-2040, as applicable, demonstrating that the proposed AU is qualified by training and experience for the use requested. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.

AND

We will provide a written attestation, signed by a preceptor AU, that the above training and experience as specified in 12 VAC 5-481-1910; 12 VAC 5-481-1940; 12 VAC 5-481-1980; 12 VAC 5-481-2010; 12 VAC 5-481-2040 as applicable, has been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized user. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.

AND, IF APPLICABLE

- We will provide a description of recent related continuing education and experience as required by 12 VAC 5-481-1790.
-

Item 5.3 Authorized Nuclear Pharmacist (ANP) (Check all that apply and attach evidence of training and experience)

Not applicable

We will provide the name(s) of the authorized nuclear pharmacist(s).

AND ONE OF THE FOLLOWING FOR EACH ANP

We will provide the previous license number (if issued by VDH) or a copy of the license (if issued by the NRC or an Agreement State) on which the individual was specifically named ANP.

OR

We will provide a copy of the certification(s) for the radiopharmacy board(s) approved by VDH.

AND

We will provide a written attestation, signed by a preceptor ANP, that the training and experience as specified in 12 VAC 5-481-1770 has been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.

OR

We will provide a description of the training and experience specified in 12 VAC 5-481-1770 demonstrating that the proposed ANP is qualified by training and experience. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.

AND

We will provide a written attestation, signed by a preceptor ANP, that the training and experience as specified in 12 VAC 5-481-1770 has been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.

AND, IF APPLICABLE

We will provide a description of recent related continuing education and experience as required by 12 VAC 5-481-1790.

Item 5.4 Authorized Medical Physicist (AMP) (Check all that apply and attach evidence of training and experience)

Not applicable

**COMPLETE ONLY IF REQUESTING LICENSE AUTHORIZATION FOR:
HDR, GAMMA STEREOTACTIC RADIOSURGERY UNIT, TELE THERAPY OR OPHTHALMIC USE**

We will provide the name(s) of the authorized medical physicist(s).

AND ONE OF THE FOLLOWING FOR EACH AMP

We will provide the previous license number (if issued by VDH) or a copy of the license (if issued by the NRC or an Agreement State) on which the individual was specifically named AMP.

OR

We will provide a copy of the certification(s) for the board(s) approved by VDH.

AND

We will provide a written attestation, signed by a preceptor AMP, that the training and experience as specified in 12 VAC 5-481-1760 has been completed and the individual has achieved a level of competency sufficient to function independently as an authorized medical physicist. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.

OR

We will provide a description of the training and experience specified in 12 VAC 5-481-1760 demonstrating that the proposed AMP is qualified by training and experience. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.

AND

We will provide a written attestation, signed by a preceptor AMP, that the above training and experience as specified in 12 VAC 5-481-1760 has been completed and the individual has achieved a level of competency sufficient to function independently as an authorized medical physicist. See Appendix B of VAREG "Guidance for Medical Use of Radioactive Material" for a form that may be used for this purpose.

AND, IF APPLICABLE

We will provide a description of recent related continuing education and experience as required by 12 VAC 5-481-1790.

TRAINING FOR WORKERS

Item 6 Training For Individuals Working In Or Frequenting Restricted Areas (Check one box)

We will follow the training programs described in Appendix H of VAREG "Guidance for Medical Uses of Radioactive Material".

OR

We will develop and implement and maintain a training program that will meet the criteria in the section titled 'Training for Individuals Working in or Frequenting Restricted Areas' of VAREG "Guidance for Medical Use of Radioactive Material." (Description is attached)

RADIOACTIVE MATERIAL

Item 7.1 Purpose(s) For Which Licensed Radioactive Material Will Be Used. (Attach additional pages if necessary)

Type of Use – Check Box if Use is Desired	Chemical and Physical Form	Maximum Amount (Curies)	Sealed Source Manufacturer or Distributor Model Number	Device Manufacturer or Distributor Model Number
<input type="checkbox"/> Use of Radioactive Material for Certain In-Vitro Clinical or laboratory testing if maximum activity exceeds 200 μ Ci 12 VAC 5-481-430(G)	Any	As needed	N/A	N/A
<input type="checkbox"/> Use of Calibration, Transmission, and Reference Sources not included in 12 VAC 5-481-1830 (e.g., bone densitometry sources, fluorine-18 calibration sources)	Attach a detailed description of the radioactive material and intended use.		N/A	N/A
<input type="checkbox"/> Unsealed Radioactive Material for Uptake, Dilution and Excretion Studies for Which a Written Directive is not Required 12 VAC 5-481-1900	Any	As needed	N/A	N/A
<input type="checkbox"/> Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is not Required 12 VAC 5-481-1920	Any	As needed	N/A	N/A
<input type="checkbox"/> Unsealed Radioactive Material for Which a Written Directive is Required 12 VAC 5-481-1950	Any		N/A	N/A
<input type="checkbox"/> Unsealed Radioactive Material for Which a Written Directive is Required Specific radiopharmaceuticals 12 VAC 5-481-1950	For this type of use attach a detailed description of radiopharmaceutical, form, route of administration and therapeutic use.		N/A	N/A
<input type="checkbox"/> Sources for Manual Brachytherapy 12 VAC 5-481-2010	Sealed Source			
Type of Use – Check Box if Use is Desired	Chemical and Physical Form	Maximum Amount (Curies)	Sealed Source Manufacturer or Distributor Model Number	Device Manufacturer or Distributor Model Number
<input type="checkbox"/> Sources for Manual Brachytherapy – Ophthalmic Use Only 12 VAC 5-481-2010	Sealed Source			

<input type="checkbox"/> Sealed Sources for Diagnosis 12 VAC 5-481-2020	Sealed Source			
<input type="checkbox"/> Sealed Source(s) in a Device for Therapy – Teletherapy Unit 12 VAC 5-481-2040	Sealed Source			
<input type="checkbox"/> Sealed Source(s) in a Device for Therapy – Remote Afterloader Unit 12 VAC 5-481-2040	Sealed Source			
<input type="checkbox"/> Sealed Source(s) in a Device for Therapy – Gamma Stereotactic Radiosurgery Unit 12 VAC 5-481-2040	Sealed Source			
<input type="checkbox"/> Other Medical Use of Radioactive Material or Radiation from Radioactive Material (e.g. Emerging Technology) 12 VAC 5-481-2060	For this type of use attach a detailed description of the radioactive material and intended use			
<input type="checkbox"/> Non-medical use of radioactive material	Attach a detailed description of the radioactive material and intended use.			

Item 7.2 Recordkeeping for Decommissioning and Financial Assurance

The applicant is not required to submit proof of recordkeeping for decommissioning and financial assurance during the licensing phase. This matter will be examined during an inspection.

FACILITIES

Item 8.1 Facilities Diagram (Check box and attach requested information.)

- We will submit the information in the section titled 'Facilities Diagram' in VAREG "Guidance for Medical Use of Radioactive Material."

Item 8.2 Radiation Monitoring Instruments (Check all that apply)

- We will identify the instrument type, sensitivity, range for each type of radiation detected and state whether the instrument will be used for 'measuring' or 'detection'. Additionally if only one survey instrument is to be used we will describe what is done when the survey instrument is being calibrated or repaired.

AND

- We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.

AND

- We will provide a description of the instrumentation (e.g. gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys or leak testing and analysis.

AND ONE OF THE FOLLOWING

- We will use radiation monitoring instruments that will be calibrated by a person authorized by VDH, the NRC or an Agreement State to perform survey meter calibrations.

OR

- We will follow survey meter calibration procedures in accordance with Appendix I of VAREG "Guidance for Medical Use of Radioactive Material."

Item 8.3 Dose Calibrator And Other Equipment Used To Measure Dosages Of Unsealed Radioactive Material (Check all that apply)

- Not applicable. (Will only use unit doses or no unsealed radioactive material use)

OR

- We will identify the instrument type, manufacturer, and model number. Additionally, if only one dose calibrator is possessed, we will describe what is done when the dose calibrator is being calibrated or repaired.

AND

- Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's

instructions.

Item 8.4 Dosimetry Equipment – Calibration And Use (Check all that apply)

**COMPLETE THIS SECTION ONLY IF REQUESTING LICENSE AUTHORIZATION FOR:
HDR, GAMMA STEREOTACTIC RADIOSURGERY UNIT, TELETHERAPY OR BRACHYTHERAPY USE**

- We will calibrate dosimetry equipment in accordance with the requirements in 12 VAC 5-481-2040.

AND

- We have developed and will implement a written calibration procedure for a therapy sealed source that meets the requirements in 12 VAC 5-481-2010 and 12 VAC 5-481-2040 (as applicable to the type of medical use requested).

AND

- We will identify the dosimetry system, manufacturer and model number.

Item 8.5 Other Equipment And Facilities (Check box and attach requested information)

- A detailed description of additional equipment and facilities available for the safe use and storage of radioactive materials requested is attached.

RADIATION PROTECTION PROGRAM

Item 9.1 Audit Program

The applicant is not required to submit its audit program to VDH for review during the licensing phase. This matter will be examined during an inspection.

Item 9.2 Occupational Dose (Check all that apply)

- We will provide a description of facilities and equipment used for monitoring occupational exposure. (Description is attached)

AND ONE OF THE FOLLOWING

- We will follow the procedures in Appendix L of VAREG "Guidance for Medical Use of Radioactive Material" for monitoring occupational dose.

OR

- We have developed and will implement written procedures for monitoring occupational dose in accordance with 12 VAC 5-481-630 that meets the requirements in 12 VAC 5-481 'Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation.' (Procedures are attached)

Item 9.3 Public Dose

No response is required, in this license application; however the licensee's evaluation of public dose will be examined during an inspection.

Item 9.4 Minimization Of Contamination (Check one box)

- We will follow the cleanup procedures from Appendix R, Tables 9 and 10, of VAREG "Guidance for Medical Use of Radioactive Material" to minimize the amount of radioactive contamination and radioactive waste generated at our facility.

OR

- We will develop, implement and maintain procedures to minimize the amount of radioactive contamination and radioactive waste generated at our facility. (Procedures are attached.)

Item 9.5 Operating And Emergency Procedures

No response is required, in this license application; however the licensee's operating and emergency procedures will be examined during an inspection.

Item 9.6 Material Receipt And Accountability (Check one box)

- Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license.

OR

- We will submit a description of the frequency and procedures for ensuring that no radioactive material has been lost, stolen or misplaced (Procedures are attached).

Item 9.7 Ordering And Receiving (Check one box)

- We will develop, implement and maintain ordering and receiving procedures that will meet the criteria in the section titled 'Ordering and Receiving' of VAREG "Guidance for Medical Use of Radioactive Material." (Procedures are attached)

OR

- We will follow procedures for ordering and receiving in accordance with Appendix O of VAREG "Guidance for Medical Use of Radioactive Material."

Item 9.8 Opening Packages

No response is required, in this license application; however the licensee's package opening procedure will be examined during an inspection.

Item 9.9 Leak Test (Check one box)

- Leak tests will be performed by an organization authorized by VDH, the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test kit supplied by an organization licensed by VDH, the NRC or another Agreement State to provide leak test kits to other licensees according to kit suppliers' instructions.

List the name and license number of organization authorized to perform or analyze leak test (Specify whether VDH, NRC, or other Agreement State):

Organization Name: _____ License Number: _____

Note: An alternate organization may be used to perform or analyze leak test, without amending the license, provided the organization is specifically authorized by VDH, the NRC or another Agreement State.

OR

- We will perform our own leak testing and sample analysis. We will follow the procedures in Appendix Q of VAREG "Guidance for Medical Use of Radioactive Material."

OR

- We will submit alternative procedures. (Procedures are attached)

Item 9.10 Area Surveys (Check one box)

- We will develop, implement and maintain procedures for area surveys that will meet the criteria in the section titled 'Area Surveys' in VAREG "Guidance for Medical Use of Radioactive Material." (Procedures are attached)

OR

- We will follow the procedures for area survey in Appendix R of VAREG "Guidance for Medical Use of Radioactive Material."

Item 9.11 Procedures For Administration of Radioactive Material Requiring A Written Directive (Check one box)

- We will develop, implement and maintain procedures for administration of radioactive material requiring a written directive that will meet the criteria in the section titled 'Procedures for Administrations Requiring a Written Directive' in VAREG "Guidance for Medical Use of Radioactive Material."

OR

- Not Applicable.
-

Item 9.12 Safe Use Of Unsealed Radioactive Material (Check one box)

- We will develop, implement and maintain procedures for the safe use of unsealed radioactive material, that will meet the criteria in the section titled 'Safe Use of Unsealed Radioactive Material' in VAREG "Guidance for Medical Use of Radioactive Material." (Procedures are attached)

OR

- We will follow the procedures for the safe use of unsealed radioactive material in Appendix T of VAREG "Guidance for Medical Use of Radioactive Material."

OR

- Not Applicable.
-

Item 9.13 Maintenance Of Therapy Devices Containing Sealed Sources (Check all that apply)

- Not Applicable. (No therapy devices containing sealed sources)

OR

- We will contract with personnel who are licensed by VDH, the NRC or another Agreement State to perform maintenance and repair services on the specific therapy device(s) possessed by the licensee.

OR THE FOLLOWING THREE CONDITIONS MUST BE MET

- We will name the proposed employee or employees and types of maintenance and repair requested.

AND

- We will provide a description of the training and experience demonstrating that the proposed employee or employees is/are qualified by training and experience for the use requested.

AND

- We will provide a copy of the manufacturer's training certification and an outline of the training.
-

Item 9.14 Spill Procedures (Check one box)

- We will develop, implement and maintain procedures for response to spills of radioactive material. (Procedures are attached.)

OR

- We will follow procedures for response to spills of radioactive material in accordance with Appendix N of VAREG "Guidance for Medical Use of Radioactive Material".

OR

- Not Applicable. (Unsealed radioactive material not used)
-

Item 9.15 Emergency Response For Sealed Sources Or Devices Containing Sealed Sources (Check one box)

- We will develop, implement and maintain procedures for emergency response for sealed sources or devices containing sealed sources. (Procedures are attached)

OR

- Not Applicable. (Brachytherapy sources, high activity sealed sources or devices containing sealed sources not used)
-

Item 9.16 Release of Patients Or Human Research Subjects (Check one box)

- We will develop, implement and maintain procedures for release of patients or human research subjects that will meet the criteria in the section titled 'Release of Patients or Human Research Subjects' in VAREG "Guidance for Medical Use of Radioactive Material." (Procedures are attached)

OR

- We will follow the procedures for release of patients or human research subjects in Appendix U of VAREG "Guidance for Medical Use of Radioactive Material."

OR

- Not applicable. (Studies only performed under 12 VAC 5-481-1900 & 12 VAC 5-481-1920)
-

Item 9.17 Mobile Medical Service (Check one box)

We will provide the information requested, along with any procedures mentioned in Appendix V of VAREG "Guidance for Medical Use of Radioactive Material." (Procedures are attached)

OR

Not applicable.

Item 9.18 Transportation

No response is needed during the license process; this issue will be reviewed during inspection.

Note: Before offering a Type B package for shipment, a licensee needs to have registered as a user of the package and obtained the agency's approval of its QA Program. Alternatively, the licensee may choose to transfer possession of radioactive material to a manufacturer (or distributor) (or service licensee) with a VDH, NRC or another agreement state license who then acts as the shipper.

- Item 9.19 Sealed Source Inventory**
- Item 9.20 Records of Dosages and Use of Brachytherapy Source**
- Item 9.21 Safety Procedures For Treatments Where Patients Are Hospitalized**
- Item 9.22 Recordkeeping**
- Item 9.23 Reporting**

No response is needed during the licensing process; these issues will be reviewed during inspection.

WASTE MANAGEMENT

Item 10 Waste Management (Check all that apply)

We will follow the waste procedures published in Appendix X of VAREG "Guidance for Medical Use of Radioactive Material."

AND / OR

We will use: Decay-In-Storage, or Disposal of Liquids Into Sanitary Sewerage waste procedures that are published in Appendix X of VAREG "Guidance for Medical Use of Radioactive Material."

AND / OR

We will provide procedures for waste collection, storage and disposal by any of the authorized methods described in Item 10 'Waste Management' of VAREG "Guidance for Medical Use of Radioactive Material." We will contact VDH for guidance to obtain approval of any method(s) of waste disposal other than those discussed in Item 10 'Waste Management' of VAREG "Guidance for Medical Use of Radioactive Material." (Procedures are attached)

Fees

Item 11 License Fees (Refer To Commonwealth of Virginia Administration Code 12 VAC 5-490)

Category:	Application Fee Enclosed (For new applications): <input type="checkbox"/> Yes <input type="checkbox"/> No Amount Enclosed: \$ _____
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CERTIFICATION (To be signed by an individual authorized to make binding commitments on behalf of the applicant.)

Item 12

I hereby certify that this application was prepared in conformance with 12 VAC 5-481 'Radiation Protection Regulations' and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.

SIGNATURE - Applicant Or Authorized Individual	Date signed
---	-------------

Print Name and Title of above signatory

Appendix B

VDH Form

‘Training and Experience and Preceptor Statement’

Appendix C

VDH Form

‘Certificate of Disposition of Materials’



CERTIFICATE OF DISPOSITION OF MATERIALS

Completion of this form is required to complete termination of a Radioactive Material License as outlined in 12 VAC 5-481-500. Failure to provide information will result in this request for termination of a specific license not being processed.

Instructions – Complete all items. Retain one copy and submit original to Virginia Department of Health (VDH), Radiological Health Program, 109 Governor Street, Room 730, Richmond, VA 23218. Telephone (804) 864-8150.

CONTACT INFORMATION

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

TERMINATION AND DISPOSITION INFORMATION

The following information is provided in accordance with 12 VAC 5-481-500 "Expiration and Termination of Licenses." (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 12 VAC 5-481-500.

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)

<input type="checkbox"/>	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 12 VAC 5-481-510 Specify the survey instrument(s) used and certify that each instrument is properly calibrated as required in 12 VAC 5-481-510.

Item 8 Records required to be maintained for the license termination requested are available at the following locations:

Name

Address

Contact Person Telephone Number (Include area code)

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 D

Information Needed for Transfer of Control

Definitions

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

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

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

Discussion

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

1. Provide a complete description of the transaction (transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact whom 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 licensed program.

Licensees should refer to NRC Information Notice 89-25, Revision 1, "Unauthorized Transfer of Ownership or Control of Licensed Activities," available on the NRC's webpage at <http://www.nrc.gov>

Appendix E

Guidance on Financial Assurance Determination

Determining Need for Financial Assurance for Decommissioning

The half-lives of unsealed radioactive material traditionally used by medical licensees have been less than 120 days. Therefore, most medical use applicants need only consider licensed material in sealed sources to evaluate the need for financial assurance. Use **Table 4** to determine if financial assurance is required for the sealed sources listed. If requesting sealed sources other than those listed or any other unsealed radioactive material with a half-life greater than 120 days, refer to **12 VAC 5-481-450 C** for possession limits requiring financial assurance. The sum of the fractions procedure is also depicted in **Table 4** and must be used to determine the need for financial assurance for both sealed and unsealed radioactive material. If the sum of the fractions is greater than 1, the applicant will need to submit financial assurance [**12 VAC 5-481-450 C**]. NRC NUREG-1757, Vol. 3, 'Consolidated NMSS Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness,' dated September 2003 contains acceptable wording for each mechanism authorized by the regulation to guarantee or secure funds.

Table 5: Worksheet for Determining Need for Financial Assurance for Sealed Sources

Step Number	Description	Cobalt-60	Cesium-137	Strontium-90
1	Activity possessed, in Curies*			
2	Activity requiring financial assurance, in Curies	10,000	100,000	1,000
3	Divide data in Step 1 by data in Step 2 for each isotope			
4	Add the fractions determined in Step 3			

* This table uses only conventional units. The conversion to the International System of units (SI) is: 1 Curie = 37 gigabecquerels.

Appendix F

Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

RSO Duties and Responsibilities

The RSO's duties and responsibilities include ensuring radiological safety and compliance with VDH and DOT regulations and the conditions of the license. Applicants may either adopt this procedure or develop alternative RSO duties and responsibilities to meet the requirements of *12 VAC 5-481-1700* as outlined below:

- Stopping unsafe activities involving licensed material;
- Radiation exposures are ALARA;
- Up-to-date radiation protection procedures in the daily operation of the licensee's radioactive material program are developed, distributed, and implemented;
- Possession, use, and storage of licensed material is consistent with the limitations in the license, the rule, the SSDR Certificate(s), and the manufacturer's recommendations and instructions;
- Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by a VDH, NRC or another Agreement State license;
- Personnel training is conducted and is commensurate with the individual's duties regarding licensed material;
- Documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided;
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- Licensed material is properly secured;
- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, and fire;
- Medical events and precursor events are investigated and reported to VDH, and cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Audits of the radiation protection program are performed at least annually and documented;
- If violations of the rule, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
- Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- Licensed material is disposed of properly;
- Appropriate records are maintained; and
- An up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner.

Model Delegation of Authority

Memo To: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

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

Signature of Management Representative

I accept the above responsibilities,

Signature of Radiation Safety Officer

cc: Affected department heads.

Model Correspondence Delegation

[date]

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

To Radioactive Material Program Director:

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

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

Signature

Title

Date

Print Name

Appendix G

**Documentation of Training and Experience for
Authorized User (AU), Radiation Safety Officer
(RSO), Authorized Nuclear Pharmacist (ANP), or
Authorized Medical Physicist (AMP)**

I. Experienced Authorized Users, Authorized Medical Physicists, Authorized Nuclear Pharmacists, or Radiation Safety Officer

An applicant or licensee that is adding an experienced authorized user, authorized medical physicist, authorized nuclear pharmacist, or radiation safety officer to its medical use license needs to provide evidence that the individual is listed on: a) a medical use license issued by VDH, NRC or another Agreement State, b) a permit issued by a NRC master material licensee, c) a permit issued by a VDH, NRC or another Agreement State medical broad scope licensee, or d) a permit issued by a NRC master material broad scope permittee before October 25, 2005. The individual must be authorized for the same types of use(s) requested in the application under review and meet the recentness of training criteria described in *12 VAC 5-481-1790*.

When adding an experienced ANP to the license, the applicant may also provide evidence that the individual is listed on: a) an NRC or Agreement State commercial nuclear pharmacy license or b) identified as an ANP by a commercial nuclear pharmacy authorized to identify ANPs. For individuals who have been previously authorized by, but not listed on, the commercial nuclear pharmacy license, medical broad scope license, or master materials license medical broad scope permit, the applicant should submit either verification of previous authorizations granted or evidence of acceptable training and experience.

II. Applicants that include individual for new Authorized User, Authorized Medical Physicist, Authorized Nuclear Pharmacist or Radiation Safety Officer recognition by VDH.

Applicants should complete the appropriate form to document that the individuals meet the appropriate training and experience criteria in *12 VAC 5-481-1700, 12 VAC 5-481-1750, 12 VAC 5-481-1760, 12 VAC 5-481-1770, 12 VAC 5-481-1780, 12 VAC 5-481-1910, 12 VAC 5-481-1940, 12 VAC 5-481-1980, 12 VAC 5-481-1990, 12 VAC 5-481-2000, 12 VAC 5-481-2010, 12 VAC 5-481-2030, 12 VAC 5-481-2040*. Forms are available for the following:

Radiation Safety Officer

Authorized Medical Physicist

Authorized Nuclear Pharmacist

Authorized User for 12 VAC 5-481-1900 & 12 VAC 5-481-1920

Authorized User for 12 VAC 5-481-1950

Authorized User for 12 VAC 5-481-2010

Authorized User for 12 VAC 5-481-2040

Forms are available on the Agency's website located at: <http://www.vdh.virginia.gov/rad/RHP-Index.asp>

There are two different training and experience routes recognized to qualify an individual as an AU, AMP, ANP or RSO. The first route is by means of certification by a professional board recognized by VDH and meeting the preceptor attestation requirements as provided in *12 VAC 5-481-1750, 12 VAC 5-481-1760, 12 VAC 5-481-1770, 12 VAC 5-481-1910, 12 VAC 5-481-1940, 12 VAC 5-481-1980, 12 VAC 5-481-1990, 12 VAC 5-481-2000, 12 VAC 5-481-2010, 12 VAC 5-481-2030, 12 VAC 5-481-2040*. The second route is by meeting the structured educational program, supervised work experience, and preceptor attestation requirements in *12 VAC 5-481-1750, 12 VAC 5-481-1760, 12 VAC 5-481-1770, 12 VAC 5-481-1780, 12 VAC 5-481-1910, 12 VAC 5-481-1940, 12 VAC 5-481-1980, 12 VAC 5-481-1990, 12 VAC 5-481-2000, 12 VAC 5-481-2010, 12 VAC 5-481-2030, 12 VAC 5-481-2040*.

III. Recentness of Training

The required training and experience described in **12 VAC 5-481 ‘Virginia Radiation Protection Regulations’, Part VII ‘Use of Radionuclides in the Healing Arts’** must be obtained within the 7 years preceding the date of the application, or the individual must document having had related continuing education, retraining, and experience since obtaining the required training and experience. Examples of acceptable continuing education and experience include the following:

- Successful completion of classroom and laboratory review courses that include radiation safety practices relative to the proposed type of authorized medical use;
- Practical and laboratory experience with patient procedures using radioactive material for the same use(s) for which the applicant is requesting authorization;
- Practical and laboratory experience under the supervision of an AU at the same or another licensed facility that is authorized for the same use(s) for which the applicant is requesting authorization; and
- For therapy devices, experience with the therapy unit and/or comparable linear accelerator experience and completion of an in-service review of operating and emergency procedures relative to the therapy unit to be used by the applicant.

IV. Instructions and guidance for filling out Training, Experience and Preceptor Attestation Form.

Note: Individuals who have been certified by boards recognized by the VDH need only complete the sections entitled ‘Name of Individual’, ‘State licensure’ (physicians and pharmacists only), ‘Certification’ and Part II ‘Preceptor Attestation’. Information for all other individuals to be listed on the license as an AU, AMP, ANP or RSO must be provided in the remaining sections of the applicable training and experience form.

Part I. Training and Experience

Provide information for each individual for whom authorization is sought. Authorized Medical Physicists should specify the type of authorization being requested.

Name of individual

Provide the individual's complete name so that VDH can distinguish the training and experience received from that received by others with a similar name. Do not include personal or private information (e.g., date of birth, social security number) as part of your qualification documentation.

State licensure

VDH requires physicians and pharmacists to be licensed by the Commonwealth of Virginia to prescribe drugs in the practice of medicine or of pharmacy, respectively (see *12 VAC 5-481-10 'Definitions'*). For AUs, attach a copy of the license to practice medicine in the Commonwealth of Virginia. For ANPs, attach a copy of the license to practice pharmacy in the Commonwealth of Virginia.

Certification

The applicant should provide the complete name of the specialty board and the category (or subspecialty) if the board recognizes more than one certification specialty. The month and year certified is used to establish recentness of training, to confirm that VDH recognizes that board's certifications, and to verify that the applicant meets the training requirements. The applicant should also provide a copy of the board certification. Board-certified applicants are reminded that they must also submit the preceptor attestation in Part II of the appropriate training and experience form.

Note: Board certifications which are accepted by VDH are listed on NRC's website at: <http://www.nrc.gov>

Medical Physicist – Formal Training

This section is used to document that the medical physicist has received one full year of full time training and one full year of work experience. Both years are required to be under the supervision of an authorized medical physicist but they do not have to be under the same authorized medical physicist.

Classroom and Laboratory Training, Supervised Work Experience, and Supervised Clinical Experience

Because the applicant is not required to receive the classroom and laboratory training at one location or at one time, space is provided to identify each location and date of training. The clock hours must be indicated for those individuals that must meet a minimum number of training and work experience hours. The specific number of hours needed for each training element will depend upon the type of approval sought. Medical physicist applicants are not required to specify the type of classroom and laboratory training they received, but they must document completion of one year of full-time training in medical physics.

All applicants will complete "Supervised Work Experience," and most individuals (e.g., under *12 VAC 5-481-1950; 12 VAC 5-481-2010*) are required to have specific clinical case experience and will complete "Supervised Clinical Experience". Applicants should list radionuclide and treatment method for each type of clinical case in which they

participate. A Radiation Safety Officer who is using the training and experience route must document one full year of work experience.

Note: Classroom and Laboratory Training may be provided at medical teaching or university institutions. In some cases, a course may be provided for that particular need and taught in consecutive days; in others, the period may be a semester or quarter as part of the formal curriculum. The required “structural educational programs” or “training” may be obtained in any number of settings, locations, and educational situations. If the applicant is seeking authorization under the requirements of *12 VAC 5-481- 1910, 12 VAC 5-481- 1940, 12 VAC 5-481-1980, 12 VAC 5-481-1990, 12 VAC 5-481-2000, 12 VAC 5-481-2010, 12 VAC 5-481-2030, 12 VAC 5-481-2040 or 12 VAC 5-481-2060*, submit a written attestation signed by a preceptor. The preceptor is responsible for the initial determination of the adequacy of the training (and work experience) to permit the individual to function independently.

Supervising Individual

Applicants should identify the individual who supervised their work experience and/or clinical case studies. If the individual had more than one supervisor, the names of all supervising individuals must be listed.

A supervisor, that is authorized for the same uses as the applicant is seeking, provides frequent direction, instruction, and direct oversight of the student as the student completes the required work experience in the use of radioactive material. Supervision may occur at various licensed facilities, from a large teaching university hospital to a small private practice. However, work experience for sealed source therapy, as described in *12 VAC 5-481-2010* and *12 VAC 5-481-2040* must have been gained at a medical institution. When the supervised work experience is complete, the applicant should provide documentation of it and written attestation from the preceptor using the appropriate training and experience form that indicates that the applicant has obtained all required experience elements.

Note: The ANP applicant is required to have supervised practical experience in a nuclear pharmacy but the individual(s) providing the supervision are not specified. Therefore the ANP applicant does not need to identify a supervising individual.

Part II Preceptor Attestation

VDH defines the term “preceptor” in *12 VAC 5-481-10, ‘Definitions,’* to mean “an individual who provides, directs or verifies training and experience requirements” for an individual to become an AU, AMP, ANP or RSO. While the supervising individual for the work experience may also be the preceptor, the preceptor does not have to be the supervising individual as long as the preceptor directs the training and experience required. The preceptor must attest in writing regarding the training and experience of any individual to serve as an AU, AMP, ANP or RSO (pursuant to *12 VAC 5-481-1750, 12 VAC 5-481-1760, 12 VAC 5-481-1770, 12 VAC 5-481-1910, 12 VAC 5-481-1940, 12 VAC 5-481-1980, 12 VAC 5-481-1990, 12 VAC 5-481-2000, 12 VAC 5-481-2010, or 12 VAC 5-481-2040*) and attest that the

individual has satisfactorily completed the appropriate training and experience criteria and has achieved a level of competence or a level radiation safety knowledge sufficient to function independently. The preceptor attests that that they are a Authorized Nuclear Pharmacist or Radiation Safety Officer or meets the requirements to be a preceptor AU, AMP. The preceptor shall sign the attestation.

Note: *12 VAC 5-481-2020, 'Use of Sealed Sources for Diagnosis'* does not require a preceptor statement.

Note: **Appendix B** contains Training, Experience and Preceptor Attestation forms.

Appendix H

Training Programs

Procedures for describing the training programs appear below. These procedures include examples of topics to be chosen from for training, based on the experience, duties, and previous training of trainees. The topics chosen will depend on the purpose of the training, the audience, and the background knowledge of the audience. These procedures also may be useful to identify topics for annual refresher training. Refresher training should include topics with which the individual is not involved frequently and require reaffirmation. Topics for refresher training need not include review of procedures or basic knowledge that the trainee routinely uses. Applicants may either adopt these procedures or develop an alternative program to meet VDH requirements. Guidance on requirements for training and experience for AMPs and AUs who engage in certain specialized practices is also included.

Training Program for Medical Uses of Radionuclides, Sealed Sources, and Medical Devices Containing Sealed Sources

Personnel will receive instruction before assuming duties with, or in the vicinity of, radioactive materials, during annual refresher training and whenever there is a significant change in duties, regulations, terms of the license, or type of radioactive material or therapy device used. Records of worker training will be maintained for at least 3 years. The training records will include the date of the instruction or training and the name(s) of the attendee(s) and instructor(s).

Training for Individuals Involved in the Usage of Radioactive Material

Training for professional staff (e.g., AU, AMP, ANP, RSO, nurse, dosimetrist, technologist, therapist) may contain the following elements for those who provide or are involved in the care of patients during diagnostic or therapeutic procedures, commensurate with their duties:

- Basic radiation biology, e.g., interaction of ionizing radiation with cells and tissues [*12 VAC 5-481-2270*];
- Basic radiation protection to include concepts of time, distance, and shielding [*12 VAC 5-481-2270*];
- Concept of maintaining exposure ALARA [*12 VAC 5-481-2270, 12 VAC 5-481-630*];
- Risk estimates, including comparison with other health risks [*12 VAC 5-481-2270*];
- Posting requirements [*12 VAC 5-481-860*];
- Proper use of personnel dosimetry (when applicable) [*12 VAC 5-481-760*];
- Access control procedures [*12 VAC 5-481-780, 12 VAC 5-481-790, 12 VAC 5-481-840*];
- Proper use of radiation shielding, if used;
- Patient release procedures [*12 VAC 5-481-1870*];
- Instruction in procedures for notification of the RSO and AU, when responding to patient emergencies or death, to ensure that radiation protection issues are identified and addressed in a timely manner. The intent of these procedures should in no way interfere with or be in lieu of appropriate patient care [*12 VAC 5-481-1960, 12 VAC 5-481-2010, 12 VAC 5-481-2040*];
- Occupational dose limits and their significance [*12 VAC 5-481-640*];
- Dose limits to the embryo/fetus, including instruction on declaration of pregnancy [*12 VAC 5-481-710*];
- Worker's right to be informed of occupational radiation exposure [*12 VAC 5-481-2280*];

- Each individual's obligation to report unsafe conditions to the RSO [12 VAC 5-481-2270];
- Applicable regulations, license conditions, information notices, bulletins, etc. [12 VAC 5-481-2260];
- Where copies of the applicable rules, the VDH license, and its application are posted or made available for examination [12 VAC 5-481-2260];
- Proper recordkeeping required by VDH rules [12 VAC 5-481-100, 12 VAC 5-481-570 12 VAC 5-481-2070];
- Appropriate surveys to be conducted, including surveys of all material leaving radioactive material areas [12 VAC 5-481-750];
- Proper use of required survey instruments [12 VAC 5-481-750];
- Decontamination and release of facilities and equipment [12 VAC 5-481-450, 12 VAC 5-481-500];
- Dose to individual members of the public [12 VAC 5-481-720]; and
- Licensee's operating procedures (e.g., survey requirements, instrument calibration, waste management, sealed source leak testing) [12 VAC 5-481-1710].

Training for the Staff Directly Involved in Administration to or Care of Patients Administered Therapeutic Quantities of Radioactive Material (Including Greater than 30 microcuries of I-131), or Therapeutic Treatment Planning

In addition to the topics identified above, the following topics may be included in instruction for staff involved in the therapy treatment of patients (e.g., nursing, RSO, AMP, AU, and dosimetrist) in the following topics, commensurate with their duties:

- Leak testing of sealed sources [12 VAC 5-481-740, 12 VAC 5-481-1840];
- Emergency procedures (including emergency response drills) [12 VAC 5-481-1960, 12 VAC 5-481-2010, 12 VAC 5-481-2040];
- Operating instructions [12 VAC 5-481-1710, 12 VAC 5-481-2010, 12 VAC 5-481-2040];
- Computerized treatment planning system [12 VAC 5-481-2040];
- Dosimetry protocol [12 VAC 5-481-2040];
- Detailed pretreatment quality assurance checks [12 VAC 5-481-1710, 12 VAC 5-481-2040];
- Safe handling (when applicable) of the patient's dishes, linens, excretions (saliva, urine, feces), and surgical dressings that are potentially contaminated or that may contain radioactive sources [12 VAC 5-481-1960, 12 VAC 5-481-2010];
- Patient control procedures [12 VAC 5-481-1960, 12 VAC 5-481-2010, 12 VAC 5-481-2040];
- Visitor control procedures, such as visitors' stay times and safe lines in radiation control areas (patient's room) [12 VAC 5-481-1960, 12 VAC 5-481-2010, 12 VAC 5-481-2040];
- Licensee's WD Procedures, to ensure that each administration is in accordance with the WD, patient identity is verified, and where applicable, attention is paid to correct positioning of sources and applicators to ensure that treatment is to the correct site (or, for GSR, correct positioning of the helmet) [12 VAC 5-481-1730];
- Proper use of safety devices and shielding to include safe handling and shielding of dislodged sources (or, in the case of remote afterloaders, disconnected sources) [12 VAC 5-481-2010, 12 VAC 5-481-2040];

- Size and appearance of different types of sources and applicators [*12 VAC 5-481-2010, 12 VAC 5-481-2040*];
- Previous incidents, events, and/or accidents [*12 VAC 5-481-1960, 12 VAC 5-481-2010, 12 VAC 5-481-2040*];
and
- For remote afterloaders, teletherapy units, and GSR units; initial training provided by the device manufacturer or by individuals certified by the device manufacturer that is device model-specific and includes:
 - Design, use, and function of the device, including safety systems and interpretation of various error codes and conditions, displays, indicators, and alarms;
 - Hands-on training in actual operation of the device under the direct supervision of an experienced user including “dry runs” (using dummy sources) of routine patient set-up and treatment and implementation of the licensee’s emergency procedures;
 - A method of determining each trainee’s competency to use the device for each type of proposed use, such as practical examinations.

Additional Training for Authorized Medical Physicists

Applicants for licenses to include AMPs who plan to engage in certain tasks requiring special training should be sure to address the sections of **12 VAC 5-481 ‘Virginia Radiation Protection Regulations’, Part VII ‘Use of Radionuclides in the Healing Arts’**-listed in *12 VAC 5-481-1760*. Note, for example, that additional training requirements apply to AMP planning tasks such as manual brachytherapy, remote afterloader therapy, teletherapy, GSR therapy and the use of the treatment planning system that applicants contemplate using. Medical physicists must also have training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system, as required in *12 VAC 5-481-1760*.

Additional Training for Therapy Authorized Users

Applicants for licenses should carefully consider the type of radiation therapy that is contemplated. In addition to the training and experience requirements of *12 VAC 5-481-1980, 12 VAC 5-481-2000, 12 VAC 5-481-2010, 12 VAC 5-481-2040*, attention should be focused on the additional training and experience required for treatment planning and quality control system, and clinical procedures. Refer to the training and experience requirements associated with specialized uses discussed in *12 VAC 5-481-1980, 12 VAC 5-481-2010, 12 VAC 5-481-2040*.

Training for Ancillary Staff

For the purposes of this section, ancillary staff includes personnel engaged in janitorial and/housekeeping duties, dietary, laboratory, security and life-safety services. The training program for ancillary staff who perform duties that are likely to result in a dose in excess of 1 mSv (100 mrem) will include instruction commensurate with potential radiological health

protection problems present in the work place. Alternatively, prohibitions on entry into controlled or restricted areas may be applied to ancillary personnel unless escorted by trained personnel. Topics of instruction may include the following:

- Storage, transfer, or use of radiation and/or radioactive material [*12 VAC 5-481-2270*];
- Potential biological effects associated with exposure to radiation and/or radioactive material, precautions or procedures to minimize exposure, and the purposes and functions of protective devices (e.g., basic radiation protection concepts of time, distance, and shielding) [*12 VAC 5-481-2270*];
- The applicable provisions of **12 VAC 5-481 ‘Virginia Radiation Protection Regulations’** and licenses for the protection of personnel from exposure to radiation and/or radioactive material (e.g., posting and labeling of radioactive material) [*12 VAC 5-481-2270*];
- Responsibility to report promptly to the licensee any condition that may lead to or cause a violation of **12 VAC 5-481 ‘Virginia Radiation Protection Regulations’** and licenses or unnecessary exposure to radiation and/or radioactive material (e.g., notification of the RSO regarding radiation protection issues) [*12 VAC 5-481-2270*];
- Appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material [*12 VAC 5-481-2270*]; and
- Radiation exposure reports that workers may request [*12 VAC 5-481-2280*].

Appendix I

Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

Model procedures for describing the specifications for monitoring instruments and a program for calibration of survey instruments appear below. Applicants may either adopt these model procedures or adopt alternative procedures.

Facilities and Equipment

- To reduce doses received by individuals not calibrating instruments, calibrations should 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, if required.

Equipment Selection

- Low-energy beta emitters, such as carbon-14 and sulfur-35, are difficult to detect with Geiger-Mueller (GM) probes. The detection efficiency generally is about 2% for low-energy beta emitters. The proper surveying method (e.g., speed and height above surface) is important to perform adequate surveys. Additionally, wipes should be taken and counted on a liquid scintillation counter to verify potential contamination.
- Medium- to high-energy beta emitters, such as P-32 and Ca-45, can be detected with a pancake GM. The efficiency ranges from 15% to 40%, depending on the beta energy.
- Low-energy gamma emitters, such as I-125, can be detected with a sodium iodide (NaI) probe or a thin window GM probe (pancake or thin end-window). If the sodium iodide probe possesses a thin window and thin crystal, the detection efficiency is approximately 20%. If a pancake or thin end-window GM probe is used, the detection efficiency is significantly lower and care should be taken to ensure that the GM probe is capable of detecting the trigger levels.
- Medium- to high-energy gamma emitters, such as I-131, can be detected with either GM or sodium iodide probes, depending on the required sensitivity. In general, the sensitivity of GM probes is much lower than for sodium iodide probes.
- The following table (except for items marked with a *), extracted from '*The Health Physics & Radiological Health Handbook*,' Revised Edition, 1992, may be helpful in selecting instruments:

Table 6: Typical Survey Instruments

Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	Radiation	Energy Range	Efficiency
Exposure Rate Meters	Gamma, X-ray	mR-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
Liquid Scintillation Counter*	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%

Procedure for Calibrating Survey Instruments

This provides acceptable procedures for survey instrument calibrations. You may either adopt these model procedures or develop your own procedures to meet the requirements of *12 VAC 5-481-630* and *12 VAC 5-481-1810*. (Detailed information about survey instrument calibration may be obtained by referring to ANSI N323A-1997, 'Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments.' Copies may be obtained from the American National Standards Institute at 1430 Broadway, New York, NY 10018 or by ordering electronically from <http://www.ansi.org>.)

Procedures for calibration of survey instruments:

- Radiation survey instruments will be calibrated with a radioactive source in accordance with *12 VAC 5-481-1810*. Electronic calibrations alone are not acceptable. Survey meters must be calibrated at least annually,

before first use and after servicing or repairs that may affect calibration. Battery changes are not considered “servicing.” Instruments used to monitor higher energies are most easily calibrated in known radiation fields produced by sources of gamma rays of approximately the same energies as those to be measured. An ideal calibration source would emit the applicable radiation (e.g., alpha, beta, or gamma) with an energy spectrum similar to that to be measured and have a suitably long half-life.

- Use radioactive sealed source(s) that:
 - Approximates a point source;
 - Is certified, NIST-traceable, standard source that has an activity or exposure rate is accurate to within 5%; if the activity or exposure rate is determined by measurement, document the method used to make the determination and traceability to NIST;
 - Emit the type of radiation measured;
 - Approximate the same energy (e.g., Cs-137, Co-60) as the environment in which the calibrated device will be employed; and
 - Provide a radiation dose rate sufficient to reach the full scale (<1000 mR/hr) of the instrument calibrated.
- Use the inverse square and radioactive decay laws, as appropriate, to correct for changes in exposure rate due to changes in distance or source decay.
- A record must be made of each survey meter calibration and retained for 3 years after each record is made [*12 VAC 5-481-1000 and 12 VAC 5-481-2070*].
- Before use, perform daily operational-calibration (with a dedicated check source) and battery checks.
- Instrument readings should be within $\pm 10\%$ of known radiation values at calibration points; however, readings within $\pm 20\%$ are acceptable if a calibration chart or graph is prepared and made available with the instrument.
- The kinds of scales frequently used on radiation survey meters are calibrated as follows:
 - Linear Readout Instruments must be calibrated at no fewer than two points on each scale. Calibration will be checked near the ends of each scale (at approximately 20% and 80%).
 - Logarithmic Readout Instruments must be calibrated at one point (the midpoint) on each decade.
 - Digital Readout Instruments with either manual or automatic scale switching for indicating exposure rates must be calibrated at no fewer than two points on each scale. Calibration will be checked near the ends of each scale (at approximately 20% and 80% of each scale).
 - Digital readout instruments without scale switching for indicating exposure rates must be calibrated at one point (the midpoint) on each decade.
 - Integrating instruments must be calibrated at two dose rates (at approximately 20% and 80% of the dose rate range).
- Readings above 1000 mR/hr (250 microcoulomb/kilogram of air per hour) need not be calibrated; however, such scales may be checked for operation and approximately correct response.
- Include in survey meter calibration records the procedure used and the data obtained. Record the following:

- A description of the instrument, including the manufacturer's name, model number, serial number, and type of detector;
- A description of the NIST-traceable calibration source, including the calibration procedure, exposure rate, distance at which it was measured and date of measurement;
- For each calibration point, the calculated exposure rate, the indicated exposure rate, the calculated correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;
- The exposure reading indicated with the instrument in the "battery check" mode (if available 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 the radiation flux field and a specified surface of the instrument;
- For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;
- The exposure 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:
 - The source that was used to calibrate the instrument;
 - The proper deflection in the battery check mode (unless this is clearly indicated on the instrument);
 - Special use conditions (e.g., an indication that a 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 from the check source, if used.

Determining the Efficiency of NaI(Tl) Uptake Probes

Sodium iodide (thallium doped) [NaI(Tl)] uptake probes are commonly used for bioassays of personnel administering I-131. Refer to *12 VAC 5-481-3690* for the Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) for occupational exposure to radionuclides. Convert count rates (e.g., in cpm) to units of activity (dpm, μCi) when performing bioassays to determine thyroid burdens of radioiodines. Use the following procedure to calibrate probe for uptake measurements:

- Frequency: perform calibrations annually, before first use and after repairs that affect calibrations;
- Check the instrument's counting efficiency using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards will be within $\pm 5\%$ of the stated value and traceable to a primary radiation standard such as those maintained by NIST.
- Calculate efficiency of the instrument.

For example:

$$Eff_a = \frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{(\text{activity of std in microcurie})}$$

Where:

Eff_a = efficiency

cpm = counts per minute

std = standard, and

bkg = background

Note: The absolute efficiency is dependent on the counting geometry. Applicants may elect to use the intrinsic efficiency, which no longer includes the solid angle subtended by the detector and has much less of a dependence on the counting geometry.

Operational and calibration checks, using a dedicated check source, should be conducted on each day the instrument is used.

The date of the efficiency test will be attached to the instrument as a calibration sticker or tag and the following information should be included:

- The date of the next efficiency due;
- Results of efficiency calculation(s).

Calculating the Gamma Well Efficiency of Counting Equipment

Gamma well counting equipment is often used for assaying the wipe testing of packages, sealed sources, and areas where unsealed radioactive material is prepared, administered, or stored. Converting cpm to dpm using smear wipes is required when dealing with radiation surveys of sealed and unsealed radioactive materials. Calculate the efficiency of all instruments used for assaying wipe tests on an annual basis, before first use, and after repair, using the following procedure:

- Check the instrument's counting efficiency, using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards will be within $\pm 5\%$ of the stated value and traceable to a primary radiation standard such as those maintained by NIST.
- Calculate efficiency of the instrument.

For example:

$$Eff = \frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{(\text{activity of std in microcurie})}$$

Where:

Eff = efficiency, in cpm / microcurie,

cpm = counts per minute

std = standard, and

bkg = background

Operational and calibration checks, using a dedicated check source, should be conducted on each day the instrument is used.

The date of the efficiency test will be attached to the instrument as a calibration sticker or tag and the following information should be included:

- The date of the next efficiency due and
- Results of efficiency calculation(s).

Reference: NUREG-1556, Vol. 18, 'Program Guidance About Service Provider Licenses' dated November 2000

Appendix J

Model Emergency Procedures for Manual Brachytherapy Permanent Implants

Applicants may either adopt **Appendix J** or develop alternative procedures to meet the requirements of *12 VAC 5-481-630*.

Lost Implant Seeds in the Operating Room

1. A calibrated and operable survey meter appropriate to the energy of the sources being used (i.e., low energy gamma detector), shielded container and forceps shall be available in the operating room during seed implantation.
2. A representative of Radiation Oncology must be present during seed implantation.
3. Once a source is known to be missing, no one shall leave the operating room until further notice.
4. Ensure that all known radiation sources are shielded.
5. Survey the room, including personnel and equipment, with a survey meter. Persons who have been surveyed and are free of contamination may be released from the operating room.
6. If the missing source is not found, notify the Radiation Safety Officer immediately.
7. If the missing source is found, use forceps to pick up the source and place it into the shielded container. Continue to survey the room to ensure that all sources have been found.

Note: A report to VDH may be required pursuant to *12 VAC 5-481-1090*.

Rupture of a Manual Brachytherapy Source

Manual brachytherapy sources for permanent implants are contained in titanium tubes and are susceptible to damage through improper handling (e.g., stepping on a source, cutting a source, or bending it with forceps or tweezers). AAPM recommends reverse action tweezers be used to prevent damage or rupture of brachytherapy seeds.

1. A calibrated and operable survey meter appropriate to the energy of the sources being used (i.e., low energy gamma detector), shielded container and forceps shall be available in the operating room during seed implantation.
2. If a source rupture is suspected, ensure that no one leaves the operating room.
3. Notify Radiation Safety Officer.
4. Shield all known sources of radiation. Use forceps to pick up source fragments and place in the shielded container.
5. Ensure that the patient and linens are not contaminated before removing patient from operating room.
6. Survey room including personnel and equipment, with a survey meter. Persons who have been surveyed and are free of contamination may be released from the operating room.
7. Decontaminate personnel and equipment as needed. Bag waste and hold for decay-in-storage.

Note: A report to VDH may be required pursuant to *12 VAC 5-481-1100*.

RSO	WORK PHONE NUMBER	EMERGENCY NUMBER

Appendix K

Suggested Medical Licensee Audit

Suggested Medical Licensee Audit

Annual Radiation Protection Medical Licensee Audit

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

Date of This Audit: _____

Date of Last Audit: _____

Next Audit Date: _____

Auditor: _____
(Signature)

Date: _____

Management Review: _____
(Signature)

Date: _____

Audit History

- A. Were previous audits conducted annually [*12 VAC 5-481-630*]?
- B. Are records of previous audits being maintained for three years after they were made [*12 VAC 5-481-990*]?
- C. Were any deficiencies identified during previous audit?
- D. Were corrective actions taken? (Note: Look for repeated deficiencies).

Organization and Scope of Program

- A. Radiation Safety Officer:
 - 1. If the RSO position has changed, was license amended [*12 VAC 5-481-1680*]?
 - 2. Does the new RSO meet the department's training requirements [*12 VAC 5-481-1750, 12 VAC 5-481-1780, 12 VAC 5-481-1790*]?
 - 3. Is the RSO fulfilling all of his/her duties [*12 VAC 5-481-1700*]?
 - 4. Is the written agreement in place for new RSO [*12 VAC 5-481-1700*]?
- B. Multiple places of radioactive material use? If yes, list all locations of use.
- C. Are all locations of use listed on the license?
- D. Were annual audits performed at each location [*12 VAC 5-481-630*]? If no, explain.
- E. Describe scope of the program (staff size, number of procedures performed, etc.).
- F. Licensed Material:
 - 1. The isotope, the chemical forms, the quantity and authorized use is listed. [L/C]
 - 2. Does the total amount of radioactive material possessed require financial assurance [*12 VAC 5-481-450 C*]? If so, is financial assurance adequate [*12 VAC 5-481-450 C*]?

3. Calibration, transmission, and reference sources [12 VAC 5-481-1830]?

- a. Sealed sources manufactured and distributed by a person licensed pursuant to the department [12 VAC 5-481-470 K], NRC, or equivalent Agreement State regulations who is authorized to redistribute sealed sources that do not exceed 1.11GBq (30 mCi) each [12 VAC 5-481-1830].
- b. Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 0.555 GBq (15 mCi) [12 VAC 5-481-1830]?
- c. Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200uCi) or 10³ times the quantities in 12 VAC 5-481-3750?
- d. Technetium-99m in amounts as needed [12 VAC 5-481-1830]?

4. Unsealed materials used under 12 VAC 5-481-1900, 12 VAC 5-481-1920, and 12 VAC 5-481-1950 are:

- a. Obtained from a manufacturer or preparer licensed under [12 VAC 5-481-470 J]?
OR
- b. Prepared by a physician authorized user, an authorized nuclear pharmacist, or an individual under the supervision of an authorized nuclear pharmacist or physician authorized user?
OR
- c. Obtained and prepared for research in accordance with 12 VAC 5-481-1900, 12 VAC 5-481-1920, and 12 VAC 5-481-1950, as applicable?

- G. Are the sealed sources possessed and used as described in the Sealed Source and Device Registration (SSDR) Certificate [12 VAC 5-481-1700, 12 VAC 5-481-2010, 12 VAC 5-481-2030, and 12 VAC 5-481-2040]? Are copies of (or access to) SSDR Certificates possessed? Are manufacturers' manuals for operation and maintenance of medical devices possessed?
- H. Are the actual uses of medical devices consistent with the authorized uses listed on the license?
- I. If places of use changed, was the license amended [12 VAC 5-481-1680]?
- J. If control of the license was transferred or bankruptcy filed, was the department's prior consent obtained or notification made, respectively [12 VAC 5-481-490 and 12 VAC 5-481-500]?

Radiation Safety Program

- A. Minor changes or revision to radiation safety program [12 VAC 5-481-1700]?
- B. Records of changes maintained for 5 years [12 VAC 5-481-2070]?
- C. Content and implementation reviewed annually by the licensee [12 VAC 5-481-630]?
- D. Records of annual reviews maintained 3 years after the date on which they were made [12 VAC 5-481-990]?

Use by Authorized Individuals

Compliance is established by meeting at least one criterion under each category.

- A. Authorized Nuclear Pharmacist [12 VAC 5-481-1770, 12 VAC 5-481-1780, 12 VAC 5-481-1790]

Note: Does not apply to facilities that are registered/licensed by FDA/State Agency as a drug manufacturer with distribution regulated under 12 VAC 5-481-480 J:

- _____ 1. Certified by specialty board
- _____ 2. Identified on VDH, NRC or another Agreement State license

- _____ 3. Identified on a permit issued by a broad scope or master materials licensee.
- _____ 4. Listed on current facility license.

B. Authorized User [*12 VAC 5-481-1780, 12 VAC 5-481-1790, 12 VAC 5-481-1910, 12 VAC 5-481-1940, 12 VAC 5-481-1980, 12 VAC 5-481-1990, 12 VAC 5-481-2000, 12 VAC 5-481-2010, 12 VAC 5-481-2030, 12 VAC 5-481-2040*]

- _____ 1. Certified by specialty board
- _____ 2. Identified on VDH, NRC or another Agreement State license
- _____ 3. Identified on permit issued by a broad scope or master materials licensee
- _____ 4. Listed on current facility license

C. Authorized Medical Physicist [*12 VAC 5-481-1760, 12 VAC 5-481-1780, 12 VAC 5-481-1790*]:

- _____ 1. Certified by specialty board
- _____ 2. Identified on VDH, NRC or another Agreement State license
- _____ 3. Identified on permit issued by broad scope or master materials licensee
- _____ 4. Listed on current facility license

Mobile Medical Service:

- A. Operates services per *12 VAC 5-481-1880, 12 VAC 5-481-2040*?
- B. Compliance with *12 VAC 5-481-720* has been evaluated and met?
- C. Letter signed by management of each client [*12 VAC 5-481-1880*]?
- D. Licensed material was not delivered to client's address (unless the client is licensed to receive radioactive materials) [*12 VAC 5-481-1880*]?
- E. Dosage measuring instruments are checked for proper function before used at each address of use or on each day of use, whichever is more frequent [*12 VAC 5-481-1880*]?
- F. Survey instruments are checked for proper operation before used at each address of use [*12 VAC 5-481-1880*]?
- G. Survey of all areas of use prior to leaving each client address [*12 VAC 5-481-1880*]?
- H. Additional technical requirements for mobile remote afterloaders are per [*12 VAC 5-481-2040*]?

Amendments Since Last Audit:

- A. Any amendments since last inspection [*12 VAC 5-481-1680*]?

Notifications Since Last Audit:

- A. Any notifications since last audit [*12 VAC 5-481-1690*]?
- B. Appropriate documentation provided to the department for Authorized Nuclear Pharmacist (ANP), Authorized Medical Physicists (AMP), or Authorized User (AU) no later than 30 days after the individual starts work [*12 VAC 5-481-1690*]?
- C. VDH notified within 30 days after: authorized user, authorized nuclear pharmacist, authorized medical physicist, or RSO stops work or changes name; licensee's mailing address changes; licensee's name changes without a transfer of control of the license; or licensee has added to or changed an area of use for *12 VAC 5-481-1900* or *12 VAC 5-481-1930* use *12 VAC 5-481-1690*?

Training, Retraining, And Instructions to Workers

- A. Have workers been provided with all required instructions [*12 VAC 5-481-2270, 12 VAC 5-481-1710, 12 VAC 5-481-1960, 12 VAC 5-481-2010, 12 VAC 5-481-2040*]?
- B. Is the individual worker understanding of current procedures and VDH rules adequate?
- C. Training program implemented?
1. Operating procedures [*12 VAC 5-481-1710, 12 VAC 5-481-1960, 12 VAC 5-481-2010, 12 VAC 5-481-2040*]?
 2. Emergency procedures [*12 VAC 5-481-1710, 12 VAC 5-481-1960, 12 VAC 5-481-2010, 12 VAC 5-481-2040*]?
 3. Periodic training required and implemented [*12 VAC 5-481-1960, 12 VAC 5-481-2010, 12 VAC 5-481-2040*]?
 4. Were all workers who are likely to exceed 1.0 mSv (100 mrem) in a year instructed, and was refresher training provided [*12 VAC 5-481-2270*]?
 5. Was each supervised user instructed in the licensee's written radiation protection procedures and administration of written directives, as appropriate [*12 VAC 5-481-1710*]?
 6. Are initial and periodic training records maintained for each individual for three years [*12 VAC 5-481-2070*]?
 7. Briefly describe training program:
- D. Additional therapy device instructions/training:
1. Unit operation, inspection, associated equipment, survey instruments?
 2. License conditions applicable to the use of the unit [**L/C**]?
 3. Emergency drills [*12 VAC 5-481-2040*]
- E. Workers cognizant of requirements for:
1. Radiation Safety Program [*12 VAC 5-481-1700, 12 VAC 5-481-630*]?
 2. Annual dose limits [*12 VAC 5-481-640, 12 VAC 5-481-720, 12 VAC 5-481-730*]?
 3. VDH Form '*Occupational Exposure Record Per Monitoring Period*'
 4. 10% monitoring threshold [*12 VAC 5-481-760*]?
 5. Dose limits to embryo/fetus and declared pregnant worker [*12 VAC 5-481-710*]?
- Note:** VAREG 8.13 '*Instructions Concerning Prenatal Radiation Exposure*' is a useful reference.
6. Extreme Danger/Grave Danger Posting [*12 VAC 5-481-860*]?
 7. Procedures for opening packages [*12 VAC 5-481-900*]?
- F. Supervision of individuals by authorized user and/or authorized nuclear pharmacist in accordance with *12 VAC 5-481-1710*?

Manual Brachytherapy and Unsealed Therapy Training

A. Safety instruction to personnel provided include [*12 VAC 5-481-1960, 12 VAC 5-481-1960*]:

1. Control of patient and visitors?
2. Routine visitation to patients in accordance with *12 VAC 5-481-720*?
3. Contamination control and size/appearance of sources?
4. Safe handling and shielding instructions?
5. Waste control?
6. RSO and AU notification in emergency or patient death?
7. Records of training retained for three years [*12 VAC 5-481-2070*]?

Facilities

A. Facilities as described in license application [**L/C**]?

B. Therapy device facilities provided with electrical interlock system, viewing and intercom systems, radiation monitor, source retraction mechanism, and source indicator lights [*12 VAC 5-481-2040, 12 VAC 5-481-780*]?

C. Emergency source recovery equipment available [*12 VAC 5-481-2010, 12 VAC 5-481-2040*]?

D. Storage areas:

1. Materials secured from unauthorized removal or access [*12 VAC 5-481-840*]?
2. Licensee controls and maintains constant surveillance of licensed material not in-storage [*12 VAC 5-481-840*]?

E. Therapy unit operation:

1. Unit, console, console keys, and treatment room controlled adequately [*12 VAC 5-481-840, 12 VAC 5-481-2040*]?
2. Restricted to certain source orientations and/or gantry angles?
3. Ceases to operate in restricted orientation(s)?
4. Only one radiation device can be operated at a time within the treatment room [*12 VAC 5-481-2040*]?

Dose or Dosage Measuring Equipment

A. Possession, use, calibration, and check of instruments to measure activities of unsealed radionuclides [*12 VAC 5-481-1800*]:

1. List type of equipment used:
2. Approved procedures for use of instrumentation followed?

3. Constancy, accuracy, linearity, and geometry dependence tests performed in accordance with nationally recognized standards or the manufacturer's instructions?
4. Instrument repaired or replaced or dosages mathematically corrected, as required, when tests do not meet the performance objectives provided in the nationally recognized standard or manufacturer's instructions (e.g., $\pm 10\%$)?
5. Records maintained and include required information [*12 VAC 5-481-2070*]?

B. Determination of dosages of unsealed radioactive material [*12 VAC 5-481-1820*]?

1. Each dosage determined and recorded prior to medical use [*12 VAC 5-481-1820*]?
2. Measurement of unit dosages made either by direct measurement or by decay correction [*12 VAC 5-481-1820*]?
3. For other than unit dosages, measurement made by direct measurement of radioactivity or by combination of radioactivity or volumetric measurement and calculation [*12 VAC 5-481-1820*]?

C. Licensee uses generators?

1. First eluate after receipt tested for Mo-99 breakthrough [*12 VAC 5-481-1930*]?
2. No radiopharmaceuticals administered with Mo-99 concentrations over 0.15 μCi per mCi of Tc-99m [*12 VAC 5-481-1930*]?
3. Records of Mo-99 concentrations maintained for 3 years [*12 VAC 5-481-2070*]?

D. Dosimetry Equipment [*12 VAC 5-481-2040*]:

1. Calibrated system available for use [*12 VAC 5-481-2040*]?
2. Calibrated by NIST or an AAPM-accredited lab within previous 2 years and after servicing [*12 VAC 5-481-2040*] or calibrated by inter-comparison per *12 VAC 5-481-2040*?
3. Calibrated within the previous 4 years [*12 VAC 5-481-2040*]?
4. Licensee has available for use a dosimetry system for spot-check measurements [*12 VAC 5-481-2040*]?
5. Record of each calibration, inter-comparison, and comparison maintained [*12 VAC 5-481-2070*]?

Radiation Protection and Control of Radioactive Material

A. Use of radiopharmaceuticals:

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

7. Syringe shields and vial shields used?

B. Leak tests and Inventories:

1. Leak test performed on sealed sources and brachytherapy sources [12 VAC 5-481-1840]?
2. Inventory of sealed sources and brachytherapy sources performed semiannually [12 VAC 5-481-1840]?
3. Records maintained for three years [12 VAC 5-481-2070]?

Radiation Survey Instruments

A. Survey instruments used to show compliance with 12 VAC 5-481, 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation' and 12 VAC 5-481-450 A 2:

1. Appropriate operable survey instruments possessed or available [12 VAC 5-481-1800]
2. Calibrations [12 VAC 5-481-1810]:
 - a. Before first use, annually and after repairs?
 - b. Within 20% on each scale or decade of interest?
3. Records maintained for three years [12 VAC 5-481-2070]?

B. Radiation surveys performed in accordance with the licensee's procedures and the regulatory requirements [12 VAC 5-481-750, 12 VAC 5-481-2040]?

1. Daily in all areas where radiopharmaceuticals requiring a written directive are prepared or administered (except patient rooms) [12 VAC 5-481-1860]?
2. Weekly in all areas where radiopharmaceuticals or waste is stored?
3. Weekly wipes in all areas where radiopharmaceuticals are routinely prepared, administered, or stored?
4. Trigger levels established?
5. Corrective action taken and documented if trigger level exceeded?
6. Techniques can detect 0.1 mR/hr, 2000dpm?
7. Surveys made to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry [12 VAC 5-481-2040] and records maintained [12 VAC 5-481-2070]?
 - a. After new source installation?
 - b. Following repairs to the source(s) shielding, the source(s) driving unit, or other electronic and mechanical mechanism that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s)?

Public Dose

- A. Is licensed material used in a manner to keep doses below 1 mSv (100 mrem) in a year [12 VAC 5-481-720]?
- B. Has a survey or evaluation been performed per 12 VAC 5-481-750?

- C. Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?
- D. Do unrestricted area radiation levels exceed 0.02 mSv (2 mrem) in any one hour [*12 VAC 5-481-720*]?
- E. Is licensed material used or stored in a manner that would prevent unauthorized access or removal [*12 VAC 5-481-840*]?
- F. Records maintained [*12 VAC 5-481-1000, 12 VAC 5-481-1050*]?

Patient Release

- A. Individuals released when TEDE less than 5 mSv (500 mrem) [*12 VAC 5-481-1870*]?
- B. Instructions to the released individual, including breast-feeding women, include required information [*12 VAC 5-481-1870*]?
- C. Release records maintained for three years [*12 VAC 5-481-2070*]?
- D. Records of instructions given to breast-feeding women maintained, if required for three years [*12 VAC 5-481-2070*]?

Radiopharmaceutical Therapy

- A. Safety precautions implemented to include patient facilities, posting, stay times, patient safety guidance, release, and contamination controls [*12 VAC 5-481-1970*]?
- B. RSO and AU promptly notified if patient died or had a medical emergency [*12 VAC 5-481-1970*]?

Brachytherapy

- A. Safety precautions implemented to include patient facilities, posting, stay times, and emergency response equipment [*12 VAC 5-481-2010*]?
- B. Survey immediately after implant [*12 VAC 5-481-2010*]?
- C. Patients surveyed immediately after removing the last temporary implant source [*12 VAC 5-481-2010*]?
- D. RSO and AU promptly notified if patient died or had a medical emergency [*12 VAC 5-481-2010*]?
- E. Records maintained for three years [*12 VAC 5-481-2070*]?

Radioactive Waste

- A. Disposal:
 1. Decay-in-storage [*12 VAC 5-481-1890*]
 2. Procedures followed [*12 VAC 5-481-1890*]?
 3. Labels removed or defaced [*12 VAC 5-481-880, 12 VAC 5-481-1890*]?
- B. Special procedures performed as required [L/C]?
- C. Improper/unauthorized disposals [*12 VAC 5-481-910*]?

D. Records maintained [*12 VAC 5-481-1000, 12 VAC 5-481-1060, 12 VAC 5-481-2070*]?

E. Effluents:

1. Release to sanitary sewer [*12 VAC 5-481-930*]?
 - a. Material is readily soluble or readily dispersible [*12 VAC 5-481-930*]?
 - b. Monthly average release concentrations do not exceed *12 VAC 5-481-3690, Table III* values?
 - c. No more than 185 GBq (5.0 Ci) of H-3, 37GBq (1.0 Ci) of C-14 and 37 GBq (1.0 Ci) of all other radionuclides combined released in a year [*12 VAC 5-481-930*]?
 - d. Procedures to ensure representative sampling and analysis implemented [*12 VAC 5-481-750*]?
2. Release to septic tanks [*12 VAC 5-481-930*]?
 - a. Within unrestricted limits *12 VAC 5-481-3690, Table III* and **12 VAC 5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation'**?
3. Waste incinerated?
 - a. License authorizes [*12 VAC 5-481-940*]?
 - b. Directly monitor exhaust?
 - c. Airborne releases evaluated and controlled [*12 VAC 5-481-730, 12 VAC 5-481-750*]?
4. Air effluents and ashes controlled [*12 VAC 5-481-630, 12 VAC 5-481-640, 12 VAC 5-481-720, 12 VAC 5-481750, 12 VAC 5-481-910*]?

Note: Useful references are NRC Inspection Procedure 87102 and NRC Regulatory Guide 8.37. These are available at www.nrc.gov.

- a. Air effluent less than 10-mrem constraint limit [*12 VAC 5-481-630*]?
- b. If no, reported appropriate information to VDH.
 - i. Corrective actions implemented and on schedule?
- c. Description of effluent program:
 - i. Monitoring system hardware adequate?
 - ii. Equipment calibrated, as appropriate?
 - iii. Air samples/sampling technique (i.e., charcoal, HEPA, etc.) analyzed with appropriate instrumentation?

F. Waste storage:

1. Protection from elements and fire?
2. Control of waste maintained [*12 VAC 5-481-840*]?
3. Containers properly labeled and area properly posted [*12 VAC 5-481-860, 12 VAC 5-481-880*]?

4. Package integrity adequately maintained?

G. Waste disposal:

1. Sources transferred to authorized individuals [*12 VAC 5-481-910, 12 VAC 5-481-100, 12 VAC 5-481-440 450*]?

2. Name of organization: _____

H. Records of surveys and material accountability are maintained [*12 VAC 5-481-1000, 12 VAC 5-481-1060, 12 VAC 5-481-2070*]?

Receipt and Transfer of Radioactive Material

A. Describe how packages are received and by whom.

B. Written package opening procedures established and followed [*12 VAC 5-481-900*]?

C. All incoming packages with a DOT label monitored for radioactive contamination, unless exempted (gases and special form) [*12 VAC 5-481-900*]?

D. Incoming packages surveyed [*12 VAC 5-481-900*]?

E. Monitoring in (C) and (D) performed within time specified [*12 VAC 5-481-900*]?

F. Transfer(s) performed per [*12 VAC 5-481-570*]?

G. All sources surveyed before shipment and transfer [*12 VAC 5-481-750, 49 CFR 173.475(i)*]?

H. Records of surveys and receipt/transfer maintained [*12 VAC 5-481-1000, 12 VAC 5-481-100*]?

I. Package receipt/distribution activities evaluated for compliance with *12 VAC 5-481-720*?

Transportation [*12 VAC 5-481-2980 and 49 CFR 171-189*]

A. Shipments are:

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

B. Return radiopharmacy doses or sealed sources?

1. Licensee assumes shipping responsibility?
2. If no, describe arrangements made between licensee and radiopharmacy for shipping responsibilities:

C. Packages:

1. Authorized packages used?

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

D. Shipping Papers:

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

Teletherapy and Gamma Stereotactic Radiosurgery Servicing

- A. Inspection and servicing performed following source replacement or at intervals not to exceed 5 years [*12 VAC 5-481-2040*]?
- B. Needed service arranged for as identified during the inspection?
- C. Service performed by persons specifically authorized to do so [*12 VAC 5-481-2040*]?

Full Calibration-Therapeutic Medical Devices

- A. Proper protocol(s) used (e.g., TG-21, AAPM 54, TG-56, TG-40, etc.)?
- B. Performed prior to first patient use [*12 VAC 5-481-2040*]?
- C. At intervals not to exceed one year for teletherapy, gamma stereotactic, and LDR remote afterloader; at intervals not exceeding one quarter for HDR, MDR, and PDR remote afterloaders [*12 VAC 5-481-2040*]?
- D. Whenever spot-checks indicate output differs from expected by $\pm 5\%$ [*12 VAC 5-481-2040*]?
- E. After source exchange, relocation, major repair or modification [*12 VAC 5-481-2040*]?
- F. Performed with properly calibrated instrument [*12 VAC 5-481-2040*]?
- G. Includes
 1. For teletherapy:
 - a. Output measured within $\pm 3\%$ of expected for the range of field sizes, range of distances [*12 VAC 5-481-2040*]?
 - b. Coincidence of radiation field and field light localizer [*12 VAC 5-481-2040*]?

- c. Uniformity of radiation field and beam angle dependence [*12 VAC 5-481-2040*]?
- d. Timer accuracy and linearity over the range of use [*12 VAC 5-481-2040*]?
- e. On-off error [*12 VAC 5-481-2040*]?
- f. Accuracy of all measuring and localization devices [*12 VAC 5-481-2040*]?

2. For remote afterloaders:

- a. Output measured within $\pm 5\%$ of expected [*12 VAC 5-481-2040*]?
- b. Source positioning accuracy within ± 1 millimeter [*12 VAC 5-481-2040*]?
- c. Source retraction with backup battery upon power failure [*12 VAC 5-481-2040*]?
- d. Length of source transfer tubes [*12 VAC 5-481-2040*]?
- e. Timer accuracy and linearity over the typical range of use [*12 VAC 5-481-2040*]?
- f. Length of the applicators [*12 VAC 5-481-2040*]?
- g. Function of source transfer tubes, applicators, and transfer tube-applicator interfaces [*12 VAC 5-481-2040*]?
- h. Autoradiograph quarterly of the LDR source(s) to verify source(s) arrangement and inventory [*12 VAC 5-481-2040*]?

3. For gamma stereotactic radiosurgery:

- a. Output measured within $\pm 3\%$ of expected [*12 VAC 5-481-2040*]?
- b. Helmet factors [*12 VAC 5-481-2040*]?
- c. Isocenter coincidence [*12 VAC 5-481-2040*]?
- d. Timer accuracy and linearity over the range of use [*12 VAC 5-481-2040*]?
- e. On-off error [*12 VAC 5-481-2040*]?
- f. Trunnion centricity [*12 VAC 5-481-2040*]?
- g. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off [*12 VAC 5-481-2040*]?
- h. Helmet microswitches [*12 VAC 5-481-2040*]?
- i. Emergency timing circuit [*12 VAC 5-481-2040*]?
- j. Stereotactic frames and localizing devices (trunnions) [*12 VAC 5-481-2040*]?

H. Output corrected mathematically for decay [*12 VAC 5-481-2040*]?

I. Records maintained for three years [*12 VAC 5-481-2070*]?

Periodic Spot Checks For Therapeutic Devices

- A. Performed at required frequency [*12 VAC 5-481-2040*]?
- B. Procedures established by authorized medical physicist [*12 VAC 5-481-2040*]?
- C. Procedures are being followed?
- D. Medical Physicist reviews results within 15 days [*12 VAC 5-481-2040*]?
- E. Performed with properly calibrated instrument [*12 VAC 5-481-2040*]?
- F. Output and safety spot checks include:
 - 1. For teletherapy:
 - a. Timer accuracy and linearity over the range of use [*12 VAC 5-481-2040*]?
 - b. On-off error [*12 VAC 5-481-2040*]?
 - c. Coincidence of radiation field and field light localizer [*12 VAC 5-481-2040*]?
 - d. Accuracy of all measuring and localization devices [*12 VAC 5-481-2040*]?
 - e. The output for one typical set of operating conditions [*12 VAC 5-481-2040*]?
 - f. Difference between measured and expected output [*12 VAC 5-481-2040*]?
 - g. Interlock systems [*12 VAC 5-481-2040*]?
 - h. Beam stops [*12 VAC 5-481-2040*]?
 - i. Source exposure indicator lights [*12 VAC 5-481-2040*]?
 - j. Viewing and intercom systems [*12 VAC 5-481-2040*]?
 - k. Treatment room doors, inside and out [*12 VAC 5-481-2040*]?
 - l. Electrical treatment doors with power shut off [*12 VAC 5-481-2040*]?
 - 2. For remote afterloaders:
 - a. Interlock systems [*12 VAC 5-481-2040*]?
 - b. Source exposure indicator lights [*12 VAC 5-481-2040*]?
 - c. Viewing and intercom systems, except for LDR [*12 VAC 5-481-2040*]?
 - d. Emergency response equipment [*12 VAC 5-481-2040*]?
 - e. Radiation monitors used to indicate source position [*12 VAC 5-481-2040*]?
 - f. Timer accuracy [*12 VAC 5-481-2040*]?

- g. Clock (date and time) in the unit's computer [12 VAC 5-481-2040]
- h. Decayed source(s) activity in the unit's computer [12 VAC 5-481-2040]?

3. For gamma stereotactic radiosurgery:

- a. Treatment table retraction mechanism [12 VAC 5-481-2040]?
- b. Helmet microswitches [12 VAC 5-481-2040]?
- c. Emergency timing circuits [12 VAC 5-481-2040]?
- d. Stereotactic frames and localizing devices [12 VAC 5-481-2040]?
- e. The output for one typical set of operating conditions [12 VAC 5-481-2040]?
- f. Difference between measured and expected output [12 VAC 5-481-2040]?
- g. Source output compared against computer calculation of output [12 VAC 5-481-2040]?
- h. Timer accuracy and linearity over the range of use [12 VAC 5-481-2040]?
- i. On-off error [12 VAC 5-481-2040]?
- j. Trunnion centricity [12 VAC 5-481-2040]?
- k. Interlock systems [12 VAC 5-481-2040]?
- l. Source exposure indicator lights [12 VAC 5-481-2040]?
- m. Viewing and intercom systems [12 VAC 5-481-2040]?
- n. Timer termination [12 VAC 5-481-2040]?
- o. Radiation monitors used to indicate room exposures [12 VAC 5-481-2040]?
- p. Emergency off buttons [12 VAC 5-481-2040]?

G. Licensee promptly repaired items found to be not operating properly and did not use unit until repaired, if required [12 VAC 5-481-2040]?

H. Records maintained for three years [12 VAC 5-481-2070]?

Installation, Maintenance, and Repair of Therapy Devices

A. Only authorized individuals perform installations, maintenance, adjustment, repair, and inspections [12 VAC 5-481-2040]? Name of organization/individual: _____

B. Records maintained for three years [12 VAC 5-481-2070]?

Operating Procedures For Therapy Devices

A. Instructions on location of emergency procedures and emergency response telephone numbers are posted at the device console [12 VAC 5-481-2040]?

B. Copy of the entire procedures physically located at the device console [12 VAC 5-481-2040]?

C. Procedures include:

1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions [12 VAC 5-481-2040]?
2. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure [12 VAC 5-481-2040]?
3. The names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally [12 VAC 5-481-2040]?

D. Radiation survey of patient is performed to ensure source is returned to shielded position [12 VAC 5-481-2040]?

E. Records of radiation surveys maintained for 3 years [12 VAC 5-481-2070]?

F. Authorized medical physicist and authorized user:

1. Physically present during initiation of patient treatment with remote afterloaders for MDR and PDR, an appropriately trained physician under the supervision of the authorized user may be physically present instead of the AU) [12 VAC 5-481-2040]?
2. Physically present throughout all patient treatments with a gamma stereotactic radiosurgery device [12 VAC 5-481-2040]?

Personnel Radiation Protection

A. Exposure evaluation performed [12 VAC 5-481-750]?

B. ALARA program implemented [12 VAC 5-481-630]?

C. External Dosimetry

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

D. Internal Dosimetry:

1. Monitor workers per 12 VAC 5-481-760?
2. Briefly describe program for monitoring and controlling internal exposures [12 VAC 5-481-810 & 12 VAC 5-481-820]?
3. Monitoring/control program implemented (includes bioassays)?
4. Respiratory protection equipment [12 VAC 5-481-830]?

E. Review of Records and Reports:

1. Reviewed by _____ Frequency _____
 2. Auditor reviewed personnel monitoring records for period _____ to _____
 3. Prior dose determined for individuals likely to receive doses [*12 VAC 5-481-680*]?
 4. Maximum exposures TEDE: _____ Other: _____
 5. Maximum CDEs: _____ Organ(s): _____
 6. Maximum CEDE: _____
 7. Internal and external summed [*12 VAC 5-481-650*]?
 8. Were occupational limits met [*12 VAC 5-481-640*]?
 9. VDH forms or equivalent used [*12 VAC 5-481-680, 12 VAC 5-481-640, 12 VAC 5-481-1020, 12 VAC 5-481-1030, 12 VAC 5-481-1040*]?
 - a. VDH Form '*Occupational Exposure Record Per Monitoring Period*'
 10. If a worker declared her pregnancy in writing during audit period, then was the dose in compliance [*12 VAC 5-481-710*] and were the records maintained [*12 VAC 5-481-1040*]?
 11. Were annual occupational exposure reports provided to workers? [*12 VAC 5-481-2280*]
- F. Who performed any planned special exposures at this facility (number of people involved and doses received) [*12 VAC 5-481-690, 12 VAC 5-481-680, 12 VAC 5-481-1030, 12 VAC 5-481-1120*]?
- G. Records of exposures, surveys, monitoring, and evaluations maintained [*12 VAC 5-481-990, 12 VAC 5-481-1000, 12 VAC 5-481-1040*]?

Confirmatory Measurements

Detail location and results of confirmatory measurements.

Medical Events

If medical events [criteria as in *12 VAC 5-481-2080*] have occurred since the last audit, evaluate the incident(s) and procedures for implementing and administering written directives using the existing guidance.

1. Event date _____ Information Source _____
2. Notifications
 - Virginia Department of Health
 - The referring physician Patient in writing/by telephone
 - If notifications did not occur, why not?
3. Written Reports [*12 VAC 5-481-2080*]:
 - a. Submitted to the agency within 15 days?

Notification and Reports

- A. In compliance with [*12 VAC 5-481-2280, 12 VAC 5-481-1100*] (reports to individuals; public and occupational doses monitored to show compliance with **12 VAC 5-481 ‘Virginia Radiation Protection Regulations’, Part IV ‘Standards for Protection Against Radiation’?**)
- B. In compliance with [*12 VAC 5-481-1090, 12 VAC 5-481-1100*] (theft or loss)?
- C. In compliance with [*12 VAC 5-481-1100*] (incidents)?
- D. In compliance with [*12 VAC 5-481-1110, 12 VAC 5-481-1100*] (overexposures and high radiation levels)?
- E. Aware of the Radioactive Materials Program phone numbers [Office: (804) 864-8150 24-hour: (800) 468-8892]
- F. In compliance with [*12 VAC 5-481-1110*] (Constraint on air emissions)?

Posting and Labeling

- A. VDH Form ‘*Notice to Employees*’ is posted [*12 VAC 5-481-2260*]?
- B. **12 VAC 5-481 ‘Virginia Radiation Protection Regulations’, Part IV ‘Standards for Protection Against Radiation’ and Part X ‘Notices, Instructions and Reports to Workers’**, license documents, operating procedures applicable to activities under the license or registration are posted or post a notice indicating where documents may be examined. [*12 VAC 5-481-2260*]?
- C. Other posting and labeling per *12 VAC 5-481-850, 12 VAC 5-481-880* and not exempted by *12 VAC 5-481-870* or *12 VAC 5-481-890*?

Recordkeeping for Decommissioning

- A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [*12 VAC 5-481-450 C*]?
- B. Records include all information outlined in *12 VAC 5-481-450 C*?

Information Notices and Regulatory Issue Summaries

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

Special License Conditions or Issues

- A. Special license conditions or issues to be reviewed:
- B. Evaluation:

Audits and Findings

- A. Summary of findings:
- B. Corrective and preventive actions:

Appendix L

Procedures for an Occupational Dose Program

This procedure provides acceptable methods for an external occupational dose program and references for developing an internal occupational dose program. Applicants may either adopt these procedures for an external occupational dose program or develop alternative procedures to meet the requirements of *12 VAC 5-481-630* and *12 VAC 5-481* ‘**Virginia Radiation Protection Regulations**’, **Part IV ‘Standards for Protection Against Radiation’**. The procedure includes guidance as well as discussion of rule requirements that are to be reflected in the elements of an occupational dose program.

“Dosimetry” is a broad term commonly applied to those methods used to measure or otherwise quantify radiation doses to individuals. A dosimetry program is required for individuals likely to receive in 1 year a dose in excess of 10% of the applicable regulatory limits in *12 VAC 5-481-640*. The Total Effective Dose Equivalent (TEDE) is the sum of the deep-dose equivalent (external exposure) and the committed effective dose equivalent (internal exposure). The definition of the terms TEDE, deep-dose equivalent (DDE), and committed effective dose equivalent (CEDE) can be found in *12 VAC 5-481-10*, ‘*Definitions*.’ To demonstrate that dosimetry is not required, the licensee needs to have available for inspection an evaluation to demonstrate that the workers are not likely to exceed 10% of the applicable annual limits (*12 VAC 5-481-750*).

If an individual is likely to receive more than 10% of the annual dose limits, VDH requires the licensee to monitor the dose, to maintain records of the dose, and, on at least an annual basis, to inform the worker of his/her dose.

The As Low As Reasonably Achievable “ALARA” Program

12 VAC 5-481-630 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 as low as is reasonably achievable (ALARA).” Additionally, *12 VAC 5-481-630* requires that licensees periodically review the content of the radiation protection program and its implementation.

External Exposure

It is necessary to assess doses to radiation workers to demonstrate compliance with regulatory limits on radiation dose and to help demonstrate that doses are maintained at ALARA levels. Providing for the safe use of radioactive materials and radiation is a management responsibility. It is important that management recognize the importance of radiation monitoring in the overall requirements for radiation protection.

There are three dose limits included in *12 VAC 5-481-640* that apply to external exposure: deep dose to the whole body (5 rem or 0.05 Sv), shallow dose to the skin or extremities (50 rem or 0.5 Sv), and dose to the lens of the eye (15 rem or 0.15 Sv). According to the definitions in *12 VAC 5-481-10*, the (DDE) to the whole body is considered to be at a tissue depth of 1 cm (1000 mg/cm²), shallow-dose equivalent to the skin or extremities at 0.007 cm (7 mg/cm²), and eye dose

equivalent at 0.3 cm (300 mg/cm²). In evaluating the eye dose equivalent, it is acceptable to take credit for the shielding provided by protective lenses.

Monitoring an individual's external radiation exposure is required by *12 VAC 5-481-760* if the external occupational dose is likely to exceed 10% of the dose limit appropriate for the individual (i.e., adult, minor, or the fetus of a declared pregnant woman). External radiation monitoring is also required by *12 VAC 5-481-760* for any individual entering a high or very high radiation area.

The use of individual monitoring devices for external exposure is required for the following:

- For adults who are likely to receive an annual dose in excess of any of the following:
 - 0.5 rem (0.005 Sv) DDE
 - 1.5 rem (0.015 Sv) eye dose equivalent
 - 5 rem (0.05 Sv) shallow-dose equivalent to the skin
 - 5 rem (0.05 Sv) shallow-dose equivalent to any extremity
- For minors who are likely to receive an annual dose in excess of any of the following:
 - rem (1.0 mSv) DDE
 - 0.15 rem (1.5 mSv) eye dose equivalent
 - 0.5 rem (5 mSv) shallow-dose equivalent to the skin
 - 0.5 rem (5 mSv) shallow-dose equivalent to any extremity.
- For declared pregnant women who are likely to receive an annual dose from occupational exposure in excess of 0.1 rem (1.0 mSv) DDE, although the dose limit applies to the entire gestation period.
- For individuals entering a high or a very high radiation area.

To demonstrate that monitoring of occupational exposure is not necessary for a group of radiation workers, it must be demonstrated that doses will not exceed 10% of the applicable limits. In these cases, VDH does not require licensees to monitor radiation doses for this class of worker.

The following methods may be used to demonstrate that doses are expected to be within 10% of rule limits:

- **Prior Experience:** Review of radiation dose histories for workers in a specific work area show that they are not likely to receive a dose in excess of 10% of the limits;
- **Area Surveys:** Demonstrate through the conduct of appropriate radiation level surveys (e.g., using a survey meter or area thermoluminescent dosimeters (TLDs)) in the work area, combined with estimates of occupancy rates and calculations, that doses to workers are not likely to exceed 10% of the limits (exposures associated with reasonable 'accident' scenarios should also be evaluated);
- The licensee performs a reasonable calculation based upon source strength, distance, shielding, and time spent in the work area, that shows that workers are not likely to receive a dose in excess of 10% of the limits.

External dose is determined by using individual monitoring devices, such as film badges, optically stimulated luminescence dosimeters (OSLs), or TLDs. These devices must be evaluated by a processor that is National Voluntary

Laboratory Accreditation Program (NVLAP)-approved, as required by *12 VAC 5-481-750*. Acceptable exchange frequencies are every 3 months for TLDs and OSLs and every month for film badges.

The device for monitoring the whole body dose, eye dose, skin dose, or extremity dose shall be placed near the location expected to receive the highest dose during the year (*12 VAC 5-481-640*). When the whole body is exposed fairly uniformly, the individual monitoring device is typically worn on the front of the upper torso.

If the radiation dose is highly non-uniform, causing a specific part of the whole body (head, trunk, arms above the elbow, or legs above the knees) to receive a substantially higher dose than the rest of the whole body, the individual monitoring device shall be placed near that part of the whole body expected to receive the highest dose. For example, if the dose rate to the head is expected to be higher than the dose rate to the trunk of the body, a monitoring device shall be located on or close to the head.

If, after the exposure is received, the licensee somehow learns that the maximum dose to a part of the whole body, eye, skin, or extremity was substantially higher than the dose measured by the individual monitoring device, an evaluation shall be conducted to estimate the actual maximum dose.

An acceptable alternative approach for highly non-uniform radiation fields is to use more than one dosimeter to separately track doses to different parts of the whole body. At the end of the year, each of the doses for each location is summed. The deep-dose equivalent recorded is that of the dosimeter location receiving the highest dose.

Because evaluation of dose is an important part of the radiation protection program, it is important that users return dosimeters on time. Licensees shall be vigorous in their effort to recover any missing dosimeters. Delays in processing a dosimeter can result in the loss of the stored information.

If an individual's dosimeter is lost, the licensee needs to perform and document an evaluation of the dose the individual received and add it to the employee's dose record. Sometimes the most reliable method for estimating an individual's dose is to use his/her recent dose history. In other cases, particularly if the individual does non-routine types of work, it may be better to use doses of co-workers as the basis for the dose estimate. It also may be possible to estimate doses by modeling and calculation (i.e., reconstruction) of scenarios leading to dose.

12 VAC 5-481-1040 requires that the recording for individual monitoring be done on VDH Form 'Occupational Exposure Record Per Monitoring Period' or equivalent. VDH Form 'Occupational Exposure Record Per Monitoring Period' is used to record doses received for the calendar year. The monitoring year may be adjusted as necessary to permit a smooth transition from one monitoring year to another, as long as the year begins and ends in the month of January, the change is made at the beginning of the year, and no day is omitted or duplicated in consecutive years. Additionally *12 VAC 5-481-2280* requires licensees to provide written annual occupational exposure reports to workers.

Investigational Levels – External Dose Monitoring

VDH emphasizes that the investigational levels in this program are not new dose limits but, as noted in ICRP Report 26, *'Recommendations of the International Commission on Radiological Protection,'* investigational levels serve as check points above which the results are considered sufficiently important to justify investigation.

In cases where a worker's or a group of workers' doses need to exceed an Investigational Level, a new, higher Investigational Level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new Investigational Levels should be documented.

When the cumulative annual exposure to a radiation worker exceeds Investigational Level I in **Table 6** (i.e., 10% of the annual limit for occupational exposure), the RSO or the RSO's designee should investigate the exposure and review the actions that might be taken to reduce the probability of recurrence. When the cumulative annual exposure exceeds Investigational Level II in **Table 6** (i.e., 30% of the annual limit for occupational exposure), the RSO or the RSO's designee will investigate the exposure and review actions to be taken to reduce the probability of recurrence, and management should review the report of the actions to be taken to reduce the probability of occurrence.

Table 7: Investigational Levels

Part of Body	Investigational Level I (mrem per year)	Investigational Level II (mrem per year)
Whole body; head; trunk including male gonads; arms above the elbow; or legs above the knee	500 (5 mSv)	1500 (15 mSv)
Hands; elbows; arms below the elbow; feet; knee; leg below the knee; or skin	5000 (50 mSv)	15,000 (150 mSv)
Lens of the eye	1500 (15 mSv)	4500 (45 mSv)

Review and record on VDH Form *'Occupational Exposure Record Per Monitoring Period'*, or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring. Take the actions list below when the investigation levels listed in **Table 6** are reached:

- Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO or the RSO's designee, no further action will be taken if an individual's dose is less than **Table 6** values for the Investigational Level I.

- Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

When the dose of an individual whose dose equals or exceeds Investigational Level I, the RSO or the RSO's designee will conduct a timely investigation and review the actions that might be taken to reduce the probability of recurrence, following the period when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action

related specifically to the exposure is required unless deemed appropriate by the RSO or the RSO's designee. Consider investigating the factors that led to the radiation exposure and the radiation doses and work habits of other individuals engaged in similar tasks to determine if improvements additional safety measures are needed to reduce exposures. Evaluate in the context of ALARA program quality and record the results of investigations and evaluations.

- Personnel dose equal to or greater than Investigational Level II.

The RSO should investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II. A consideration of actions should be taken by the RSO to reduce the probability of occurrence, and a report of the actions should be reviewed by the licensee's management at its first meeting following completion of the investigation.

- Re-establishment of Investigational Level II to a level above that listed in **Table 6**.

Declared Pregnancy and Dose to Embryo/Fetus

12 VAC 5-481-710 states that the licensee shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman. The pregnancy is declared in writing, and includes the worker's estimated date of conception, the dose to an embryo/fetus shall be taken as the sum of:

- The deep-dose equivalent to the declared pregnant woman; and
- The dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

References

- Methods for calculating the radiation dose to the embryo/fetus can be found in NRC Regulatory Guide 8.36, '*Radiation Dose to the Embryo/Fetus*.'
- NUREG/CR-5631, PNL-7445, Rev. 2, '*Contribution of Maternal Radionuclide Burdens to Prenatal Radiation Doses*' (1996).

Note: To obtain these documents contact NRC Region I or go to the NRC's web site at www.nrc.gov

Internal Exposure

With respect to internal exposure, you are required to monitor occupational intake of radioactive material and assess the resulting dose if it appears likely that personnel will receive greater than 10% of the annual limit on intake (ALI) from

intakes in 1 year. **12 VAC 5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation'**, provides terms for radionuclide intakes by means of inhalation and ingestion, i.e., derived air concentration (DAC) and ALI.

The DAC for each class of radionuclide is the concentration of airborne radioactivity in $\mu\text{Ci/ml}$ that, if an occupational worker were to be continuously exposed to for 2,000 hours (1 year), would result in either a CEDE of 5 rem (0.05 Sv) to the whole body or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue, with no consideration for the contribution of external dose. The ALI and DAC for each radionuclide in a specific chemical form are listed in **12 VAC 5-481-3690**.

For each class of each radionuclide, there are two ALIs, one for ingestion and one for inhalation. The ALI is the quantity of radioactive material that, if taken into the body of an adult worker by the corresponding route, would result in a committed effective dose equivalent of 5 rem (0.05 Sv) or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue, again, with no consideration for the contribution of external dose.

The total effective dose equivalent concept makes it possible to combine both the internal and external doses in assessing the overall risk to the health of an individual. **12 VAC 5-481-3690**, ALI and DAC numbers reflect the doses to all principal organs that are irradiated. The ALI and DAC were derived by multiplying a unit intake by the appropriate organ weighting factors (W_T), for the organs specifically targeted by the radionuclide compound, and then summing the organ-weighted doses to obtain a whole body risk-weighted "effective dose." Per **12 VAC 5-481-3690**, when an ALI is defined by the stochastic dose limit, this value alone is given. When the ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses.

The types and quantities of radioactive material manipulated at most medical facilities do not provide a reasonable possibility for an internal intake by workers. However, uses such as preparing radioiodine capsules from liquid solutions, and opening and dispensing radioiodine from vials containing millicurie quantities require particular caution. To monitor internal exposures from such operations, a routine bioassay program to periodically monitor workers should be established.

If a licensee determines that a program for performing thyroid uptake bioassay measurements is necessary, a program should be established. The program should include:

- adequate equipment to perform bioassay measurements,
- procedures for calibrating the equipment, including factors necessary to convert counts per minute into becquerel or microcurie units,
- the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue),
- the interval between bioassays,
- action levels, and

- the actions to be taken at those levels.

For guidance on developing bioassay programs and determination of internal occupational dose and summation of occupational dose, refer to NRC Regulatory Guide 8.9 Revision 1, 'Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program' dated July 1993, NRC Regulatory Guide 8.34, 'Monitoring Criteria and Methods to Calculate Occupational Radiation Doses, dated July 1992, and NUREG-1400, 'Air Sampling in the Workplace,' dated September 1993.' These documents are available by contacting the NRC or from the NRC's website: www.nrc.gov.

Recordkeeping

Records of measurement data, calculations of intakes, and methods for calculating dose must be maintained as required by *12 VAC 5-481-670, 12 VAC 5-481-1000, 12 VAC 5-481-1040*. For additional information on recordkeeping and reporting occupational exposure data, including intakes, refer to Revision 1 of NRC Regulatory Guide 8.7, '*Instructions for Recording and Reporting Occupational Radiation Exposure Data.*' This document is available by contacting the NRC or from the NRC's website: www.nrc.gov

Summation of External and Internal Doses

Pursuant to *12 VAC 5-481-640*, the external and internal doses must be summed if required to monitor both under *12 VAC 5-481-760*.

Two documents that contain helpful information regarding occupational doses are:

- NRC Regulatory Issue Summary 2002-06, '*Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays;*' and
- NRC Regulatory Issue Summary 2002-10, '*Revision of Skin Dose Unit in 10 CFR Part 20.*'

Copies of NRC Regulatory Issue Summaries are available on the NRC web site in the Electronic Reading Room http://www.nrc.gov/reading_rm/doc_collections/gen_comm/reg_issues found at www.nrc.gov.

Appendix M

RESERVED

Appendix N

Emergency Procedures

Spill Procedures – Low and High Activity Unsealed Sources

These procedures provide acceptable responses to emergencies. Applicants may either adopt **Appendix N** or develop alternative procedures to meet the requirements of *12 VAC 5-481-630*.

Spilled Gas Procedure

1. Notify persons in the room that a spill has occurred and ask them to leave the room.
2. Remove the patient from the room.
3. Close door to room.
4. Remain outside the room for ___ minutes (see below for clearance time calculation).
5. Report the incident to the RSO.

RSO	WORK PHONE NUMBER	EMERGENCY NUMBER

This spilled gas procedure shall be posted in the room(s) where gas is used.

Clearance Time Calculation

Because normal room ventilation is usually not sufficient to ensure timely clearance of spilled gas, the following calculations should be done to determine for how long a room should be cleared in case of a gas spill.

1. Collect the following data:
 - a. A, the highest activity of gas in a single container, in microcuries;
 - b. Measured airflow supply from each vent in the room (if different during heating and cooling seasons, use the lesser value), in milliliters per minute;
 - c. Q, the total room air exhaust determined by measuring, in milliliters per minute, the airflow to each exhaust vent in the room (the exhaust should be vented and not recirculated within the facility); this may be either the normal air exhaust or a specially installed gas exhaust system;
 - d. C, the maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133, the maximum permissible values are $1 \times 10^{-5} \mu\text{Ci/ml}$ in restricted areas and $3 \times 10^{-7} \mu\text{Ci/ml}$ in unrestricted areas. For other gases, see *12 VAC 5-481-3690*; and
 - e. V, the volume of the room in milliliters.
2. For each room in which radioactive gases are used, make the following calculation:
 - a. The airflow supply should be less than the airflow exhaust to ensure the room is at negative pressure.
 - b. The evacuation time $t = \frac{-V}{Q} \times \ln\left(\frac{CV}{A}\right)$

Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent paper.
3. Wearing gloves and protective clothing such as a lab coat and booties, clean up the spill using absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a "caution radioactive material" labeled bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detection survey instrument sufficiently sensitive to detect the radionuclide. Check for removable contamination to ensure contamination levels are below trigger levels. Check the area around the spill. Also check hands, clothing, and shoes for contamination.
5. Report the incident to the RSO.

Major Spills of Liquids and Solids

1. Clear the area. Notify all persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with "caution radioactive material" labeled absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, clearly indicate the boundaries of the spill and limit the movement of all personnel who may be contaminated.
3. Shield the source if possible. Do this only if it can be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry.
5. Notify the RSO immediately.
6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with mild soap. If contamination remains, the RSO may consider inducing perspiration. Then wash the affected area again to remove any contamination that was released by the perspiration.

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, likelihood of contamination spread, types of surfaces contaminated and radiotoxicity of the spilled material. For some spills of radionuclides with half-lives shorter than 24 hours and in amounts less than five times the lowest ALI, an alternative spill procedure may be to restrict access pending complete decay.

RSO	WORK PHONE NUMBER	EMERGENCY NUMBER

Note: A report to VDH may be required pursuant to *12 VAC 5-481-1100*.

Use **Table 7** as general guidance to determine whether a major spill procedure or a minor spill procedure will be implemented.

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure, based on the following information. Spills above these millicurie amounts are considered major, and below these levels are considered minor.

Table 8 Relative Hazards of Common Medical Radionuclides

Radionuclides	Millicurie	Radionuclide	Millicurie
F-18	100	Tc-99m	100
P-32	1	In-111	10
Cr-51	100	I-123	10
Co-57	10	I-125	1
Co-58	10	I-131	1
Fe-59	1	Sm-153	10
Co-60	1	Yb-169	10
Ga-67	10	Hg-197	10
Se-75	1	Au-198	10
Sr-85	10	Tl-201	100
Sr-89	1		

Spill Kit

Assemble a spill kit that contains the following items:

- Disposable gloves and housekeeping gloves;
- Disposable lab coats;
- Disposable head coverings;
- Disposable shoe covers;
- Roll of absorbent paper with plastic backing;
- Masking tape;
- Plastic trash bags with twist ties;
- “Radioactive Material” labeling tape;
- Marking pen;
- Pre-strung “Radioactive Material” labeling tags;
- Contamination wipes;
- Instructions for “Emergency Procedures”;
- Clipboard with copy of Radioactive Spill Report Form;
- Pencil; and
- Appropriate survey instruments, including batteries.

Emergency Surgery of Patients Who Have Received Therapeutic Amounts of Radionuclides

The following procedures should be followed:

1. If emergency surgery is performed within the first 24 hours following the administration of I-131 sodium iodide, fluids (e.g., blood, urine) will be carefully removed and contained in a closed system.
2. Protective eye wear will be worn by the surgeon and any personnel involved in the surgical procedure for protection of the eyes from possible splashing of radioactive material and exposure from beta radiation (if applicable).
3. The Radiation Safety Staff will direct personnel in methods to keep doses ALARA during surgical procedures.
4. If an injury occurs during surgery that results in a cut or tear in the glove used, the individual involved will be monitored to determine if radioactive material was introduced into the wound. The RSO will be informed of any possible radiation hazard.

Autopsy of Patients Who Have Received Therapeutic Amounts of Radionuclides

The following procedures should be followed:

1. Immediately notify the AU in charge of the patient and the RSO upon death of a therapy patient.
2. An autopsy will be performed only after consultation and permission from the RSO. Radiation safety staff should evaluate the radiation hazard(s), direct personnel in safety and protection, and suggest suitable procedures in order to keep doses ALARA during the autopsy.
3. Protective eyewear should be worn by the pathologist and assisting staff for protection from possible splashing of radioactive material. Consider the need for protection against exposure from high energy beta rays in cases involving therapy with P-32 and Y-90.
4. Remove tissues containing large activities early to help reduce exposure of autopsy personnel. Shield and dispose of contaminated tissues in accord with license conditions. In some cases, exposure reduction may be accomplished by removing tissues for dissection to a location where the exposure rate is lower.
5. If an injury occurs during the autopsy that results in a cut or tear in the glove, monitor the wound and decontaminate as appropriate to the situation; inform radiation safety staff.

Reference: NRC Report No. 111, "Developing Radiation Emergency Plans for Academic, Medical, and Industrial Facilities," 1991, contains helpful information. It is available from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 400, Bethesda, Maryland 20814-3095. NCRP's telephone numbers are: (301) 657-2652 or 1-800-229-2652.

Appendix O
Procedures for Ordering and Receiving Packages

This procedure provides acceptable methods for ordering and receiving packages containing licensed material. Applicants may either adopt this procedure or develop alternative procedures.

Guidance

- Authorize, through a designee (e.g., RSO), each order of radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting AU and that possession limits are not exceeded.
- Establish and maintain a system for ordering and receiving radioactive material; include the following information:
 - Records that identify the AU or department, radionuclide, physical and/or chemical form, activity, and supplier;
 - Confirmation, through the above records, that material received was ordered through proper channels.
- For deliveries during normal working hours, inform carriers to deliver radioactive packages directly to a specified area.
- For deliveries during off-duty hours, inform security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum for delivery of packages to the Nuclear Medicine Division, provided below. Develop a similar memorandum for delivery of packages to other divisions.

Sample Memorandum

MEMO TO: Chief of Security
FROM: Radiation Safety Officer
SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard on duty will accept delivery of radioactive material that arrives outside normal working hours. Packages will be taken immediately to the Nuclear Medicine Division, Room _____. Unlock the door, place the package on top of the counter, and relock the door.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our hospital Radiation Safety Officer, at extension _____.

Title	Name	After Hours Telephone Number
Radiation Safety Officer		
Director of Nuclear Medicine		
Nuclear Medicine Technologist Supervisor		
Nuclear Medicine Technologist on call		
Nuclear Medicine Physician on Call		

Appendix P

**Model Procedure for Safely Opening Packages
Containing Radioactive Material**

This model provides acceptable procedures for opening packages containing radioactive material. Applicants may either adopt this model procedure or develop an alternative procedure to meet the requirements of *12 VAC 5-481-900*.

Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in *49 CFR 173.435* or *12 VAC 5-481-3770* (e.g., 20 curies of Mo-99, 54 curies of Cs-137, 27 curies of Ir-192; 540 curies of I-125; 270 curies of Xe-133, or 110 curies of Tc-99m). Such packages must be received expeditiously when the carrier offers it for delivery or when the carrier notifies the licensee that the package has arrived at the carrier's terminal. For these and other packages for which monitoring is required, check for external radiation levels and surface contamination within 3 hours of receipt (if received during working hours) or no later than 3 hours from the beginning of the next working day (if received after working hours), in accordance with the requirements of *12 VAC 5-481-900*.

VDH and the final delivery carrier must be notified if the following conditions apply:

- Removable radioactive surface contamination exceeds the limits of *12 VAC 5-481-3070* [i.e. 22 dpm/cm² of beta or gamma emitting photons or 2.2 dpm/cm² of alpha]; and
- External radiation levels exceed the limits of *49 CFR 173.441* (200 mR/hr on contact)

Implement the following procedure for opening each package containing radioactive material received under your VDH license:

1. Put on gloves to prevent hand contamination.
2. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO immediately.
3. Monitor the external surfaces of a labeled package for radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form, as defined in *12 VAC 5-481-10*. (*Note: Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations, 49 CFR 172.403 and 172.436-440.*)
4. Monitor the external surfaces of a labeled package for radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in *12 VAC 5-481-10 and 12 VAC 5-481-3770*. (*Note: Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations, 49 CFR 172.403 and 49 CFR 172.436-440.*)
5. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels, if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.
6. Remove the packing slip.
7. Open the outer package, following any instructions that may be provided by the supplier.
8. Open the inner package and verify that the contents agree with the packing slip.
9. Check the integrity of the final source container. Notify the RSO of any broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.

10. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. An appropriate instrument with sufficient sensitivity will be used to assay the sample. For example, a NaI(Tl) crystal and rate meter, a liquid scintillation counter, or a proportional flow counter may be used for these assays. The detection efficiency will be determined to convert wipe sample counts per minute to disintegrations per minute (**Note:** a dose calibrator is not sufficiently sensitive for this measurement). Take precautions against the potential spread of contamination.
11. Check the user request to ensure that the material received is the material that was ordered.
12. Monitor the packing material and the empty packages for contamination with radiation detection survey meter before discarding. If contaminated, treat this material as radioactive waste. If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.
13. Make a record of the receipt.

For packages received under the general license in *12 VAC 5-481-430 G*, implement the following procedure for opening each package:

1. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO immediately.
2. Check to ensure that the material received is the material that was ordered.

Appendix Q
Leak Test Program

Procedures for leak testing appear below. Applicants may either adopt these procedures or develop alternative procedures.

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests should be analyzed in a low-background area.
- Consider using a NaI(Tl) well counter system with a single or multichannel analyzer to analyze samples obtained from gamma-emitting sources (e.g., Cs-137).
- Consider using a liquid scintillation or gas-flow proportional counting system to analyze samples obtained from beta-emitting sources (e.g., Sr-90).
- Instrumentation used to analyze leak test samples must be capable of detecting 185 Bq (0.005 μ Ci) of radioactivity.

Procedure for Performing Leak Testing and Analysis

This procedure provides acceptable procedures for sealed source leak testing and analysis. Applicants may either adopt this procedure or develop alternative procedures.

- For each source to be tested, list identifying information such as sealed source serial number, radionuclide, and activity.
- Use a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate identifying information for each source.
- Wear gloves.
- Obtain samples at the most accessible area where contamination would accumulate if the sealed source were leaking.
- Measure the background count rate and record.
- Check the instrument's counting efficiency, using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within $\pm 5\%$ of the stated value and traceable to a primary radiation standard, such as those maintained by NIST.
- Calculate efficiency of the instrument.

For example:

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

where:

cpm = counts per minute

std = standard

bkg = background

- Analyze each wipe sample to determine net count rate.
- For each sample, calculate the activity in microcurie and record.

For example:

$$\frac{(\text{cpm from wipe sample}) - (\text{cpm from bkg})}{\text{efficiency in cpm/microcurie}} = \text{microcurie on wipe sample}$$

- Leak test records will be retained in accordance with *12 VAC 5-481-2070* for 3 years. Include the following in records:
 - The model number and serial number (if assigned) of each source tested;
 - The identity of each source radionuclide and its estimated activity;
 - The measured activity of each test sample expressed in microcurie;
 - A description of the method used to measure each test sample;
 - The date of the test; and
 - The name of the individual who performed the test.
- If the wipe test reveals 185 Bq (0.005 μCi) or greater:
 - Immediately withdraw the sealed source from use and either store the source, dispose of the source, or cause the source to be repaired, in accordance with the requirements in *12 VAC 5-481-740*.

File a report within 5 days of the leakage test with VDH.

Appendix R
Procedure for Area Surveys

This procedure provides acceptable methods for area surveys. Applicants may either adopt these procedures or develop alternative procedures to meet the requirements of *12 VAC 5-481-630*, *12 VAC 5-481-750*, *12 VAC 5-481-1860*.

Ambient Radiation Level Surveys

Procedures for ambient radiation level surveys (reference *12 VAC 5-481-630*, *12 VAC 5-481-750*, *12 VAC 5-481-1860*):

- Perform surveys of dose rates 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
 - An individual is working in an environment with a dose rate of 2.5 mrem/hour or more (5 rem/year divided by 2,000 hour/year).
- *12 VAC 5-481-720* requires that the TEDE to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year, and that the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour. Appropriate surveys will be conducted to assure that the requirements of *12 VAC 5-481-720* are met.
- Perform radiation level surveys with a survey meter sufficiently sensitive to detect 0.1 milliroentgen (mR) per hour in the following areas, at the frequency specified:
 - Survey at the end of each day of use all radiopharmaceutical elution, preparation, assay and administration areas (except patient rooms, which will be surveyed at the end of the therapy instead of on the day of administration) when using radiopharmaceuticals requiring a written directive (e.g., all therapy dosages and any iodine-131 dosage exceeding 30 μ Ci).
 - Survey weekly all radionuclide use, storage, and waste storage areas. If diagnostic administrations are occasionally made in patients' rooms (e.g., bone scan injections, Tc-99m heart agents) and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
 - Survey monthly all laboratory areas where only small quantities of gamma-emitting radioactive material are used (< 200 μ Ci at a time).
 - Survey quarterly all sealed source and brachytherapy source storage areas.
- Notify radiation safety or the RSO immediately of radiation levels that exceed trigger levels. Trigger levels for restricted and unrestricted areas are presented in **Table 8**

Table 9 Ambient Dose Rate Trigger Levels

Type of Survey	Area Surveyed	Trigger Level
Ambient Dose Rate	Unrestricted	0.1 mR/hr
Ambient Dose Rate	Restricted	5.0 mR/hr

Contamination Surveys

Facilities and equipment for contamination surveys:

To ensure achieving the required sensitivity of measurements, analyze survey samples in a low-background area. The table entitled 'Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples' in Appendix I provides examples of appropriate instruments.

Perform contamination surveys using instruments suitable for removable and fixed contamination to identify areas of contamination that might result in doses to workers or to the public. Removable contamination can be detected and measured by conducting a wipe test of the surface, 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.

Procedures for contamination surveys:

- Contamination surveys are performed in areas where unsealed forms of materials are used:
 - 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 monthly;
 - In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.
- Use methods for conducting surveys for removable contamination that are sufficiently sensitive to detect contamination for those radionuclides in use and for which the most restrictive limits apply, as listed in **Tables 9 and 10** for unrestricted areas (e.g., 200 dpm/100 cm² for isotopes of iodine-131 in unrestricted areas). Removable contamination survey samples will be measured in a low-background area. The following areas and frequencies will be followed:
 - Removable contamination surveys weekly for radiopharmaceutical elution, preparation, assay, and administration areas. If diagnostic administrations are occasionally made in patients' rooms (i.e., bone scan injections, Tc-99m heart agents, etc.), with special care taken to remove all paraphernalia, those rooms need not be surveyed.
 - Removable contamination surveys monthly of laboratory areas where only small quantities of photon-emitting radioactive material are used (<200 microcurie at a time).
 - Removable contamination surveys weekly for radionuclide storage and radionuclide waste storage areas.

- A radioactive source with a known amount of activity will be used to convert sample measurements (usually in cpm) to dpm.
- The area should be either decontaminated, shielded, or posted and restricted from use if it cannot be decontaminated. **Note:** A report to VDH may be required under *12 VAC 5-481-1100*.
- If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Example trigger levels for unrestricted areas are presented in **Table 9**. Contamination found in unrestricted areas and on personal clothing will be immediately decontaminated to background levels.

Table 10 Surface Contamination Levels in Restricted Areas (dpm/100 cm²)

Area, clothing	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, Y-90, In-111, I-123, I-125, I-131, Sm-153, Yb-169, Lu-177, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
Restricted areas, protective clothing used only in restricted areas	2000	20000

Table 11 Surface Contamination Levels in Unrestricted Areas (dpm/100 cm²)

Nuclide ¹	Average ^{2,3,6}	Maximum ^{2,4,6}	Removable ^{2, 5, 6}
I-125, I-126, I-131, I-133, Sr-90	1,000	3,000	200
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	5,000	15,000	1,000

1. Where surface contamination by multiple nuclides exists, the limits established for each nuclide should apply independently.
2. As used in this table, dpm 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 cm².
5. The amount of removable radioactive material per 100 cm² 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.
6. The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 millirad/hour at 1 centimeter and 1.0 millirad/hour at 1 centimeter, respectively, measured through not more than 7 milligrams per square centimeter of total absorber.

Establishing Alternate Trigger Levels for Restricted Areas

The following guidance is provided for those applicants who plan to develop procedures for surveying and controlling contamination using action levels for controlling contamination that differ from those provided in **Tables 9 and 10**.

Alternate action levels for cleanup of contamination restricted areas may be developed without prior VDH approval if:

- Acceptable unrestricted area trigger levels are implemented (e.g., **Tables 8 and 10**)
- the action levels maintain occupational doses ALARA;
- the action levels meet all other regulatory requirements (e.g., they should also be designed to minimize, to the extent practicable, contamination of the facility, and the environment; facilitate eventual decommissioning; and minimize, to the extent practicable, the generation of radioactive waste).

Alternate Survey Frequency

An example alternate survey frequency is described below. The objective is to determine how often to survey the laboratory. To do this, multiply the activity range for the appropriate group 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. For instance, if 30 millicurie of iodine-131 is used in the hot laboratory, the survey frequency for the hot laboratory would be daily; since the group for iodine-131 is Group 2, the survey frequency category for an activity of greater than 10 millicurie is high, and the modifying factor is 1.

Table 12 Grouping of Radioisotopes for Alternate Survey Frequency

Group 1	Group 1, excerpted from IAEA Safety Series 115, does not include radioisotopes traditionally used in medicine.
Group 2	Co-60 Sr-90 I-125 I-126 I-131 I-133 Cs-134 Cs-137 Eu-152 (13 y) Eu-154 Ir-192 Tl-204
Group 3	C-14 F-18 Na-24 P-32 S-35 Cr-51 Fe-59 Co-57 Co-58 Se-75 Sr-85 Y-90 Mo-99 Tc-99 Rh-105 Pd-103 In-115m Sn-113 Sm-153 Eu-152 Eu-155 Gd-153 Dy-165 Yb-175 Lu-177 Au-198 Hg-197 Tl-201
Group 4	H-3 O-15 Rb-87 Tc-99m Rh-103m In-113m Xe-133 Cs-134m

Table 13 Classification of Laboratories for Alternate Survey Frequency

Group	Survey Frequency Category		
	Low	Medium	High
1	<0.1 mCi	0.1 mCi to 1 mCi	>1 mCi
2	<1 mCi	1 mCi to 10 mCi	>10 mCi
3	<100 mCi	100 mCi to 1 Ci	>1 Ci
4	<10 Ci	10 Ci to 100 Ci	>100 Ci

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.

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

Table 14 Modifying Factors for Alternate Survey Frequency

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 (including patients)	x 0.1
Dry and dusty operations (e.g., grinding)	x 0.01

Contents of Survey Records

- A diagram of the area surveyed;
- A list of items and equipment surveyed;
- Specific locations on the survey diagram where wipe tests were 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.

Record contamination levels observed and procedures followed for incidents involving contamination of individuals. 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.

Appendix S

Model Procedure for Developing, Maintaining, and Implementing Written Directives

This model provides acceptable procedures for administrations that require written directives. You may either adopt this model procedure or develop your own procedure to meet the requirements of *12 VAC 5-481-1720* & *12 VAC 5-481-1730*.

Written Directive Procedures

This model provides guidance to licensees and applicants for developing, maintaining, and implementing procedures for administrations that require WDs. This model does not restrict your use of other guidance in developing, implementing, and maintaining written procedures for administrations requiring a WD. Such procedures are to provide high confidence that the objectives specified in *12 VAC 5-481-1730* will be met.

The WD must be prepared for any administration of I-131 sodium iodide greater than 1.11 MBq (30 μ Ci), any therapeutic dosage of a radiopharmaceutical, and any therapeutic dose of radiation from radioactive material. The WD must contain the information described in *12 VAC 5-481-1720* and be retained in accordance with *12 VAC 5-481-2070*.

Discussion

The administration of radioactive materials can be a complex process for many types of diagnostic and therapeutic procedures in nuclear medicine or radiation oncology departments. A number of individuals may be involved in the delivery process. For example, in an oncology department, when the AU prescribes a teletherapy treatment, the delivery process may involve a team of medical professionals such as an AMP, a dosimetrist, and a radiation therapist. Treatment planning may involve a number of measurements, calculations, computer-generated treatment plans, patient simulations, portal film verifications, and beam-modifying devices to deliver the prescribed dose. Therefore, instructions must be clearly communicated to the professional team members with constant attention devoted to detail during the treatment process. Complicated processes of this nature require good planning and clear, understandable procedures. To help ensure that all personnel involved in the treatment fully understand instructions in the WD or treatment plan, the licensee should instruct all workers to seek guidance if they do not understand how to carry out the WD. Specifically, workers should ask if they have any questions about what to do or how it should be done before administration, rather than continuing a procedure when there is any doubt. Licensees should also consider verification of WDs or treatment plans by at least one qualified person (e.g., an oncology physician, AMP, nuclear medicine technologist, or radiation therapist), preferably other than the individual who prepared the dose, the dosage, or the treatment plan.

The administration of radioactive materials can involve a number of treatment modalities, e.g., radiopharmaceutical therapy, teletherapy, brachytherapy, gamma stereotactic radiosurgery (GSR), and future emerging technologies. For each such modality for which *12 VAC 5-481-1720* requires, or would require, a written directive (as defined in *12 VAC 5-481-10*), the licensee shall develop, implement, and maintain written procedures for WDs to meet the requirements and/or objectives of *12 VAC 5-481-1720*, *12 VAC 5-481-1730*, *12 VAC 5-481-1820*, outlined below:

- Have an authorized user date and sign a written directive prior to the administration that includes the information in *12 VAC 5-481-1720*, including the patient or human research subject's name;

- Verify the patient's or human research subject's identity prior to each administration;
- Verify that the administration is in accordance with the treatment plan, if applicable, and the written directive;
- Check both manual and computer-generated dose calculations;
- Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices; and
- Determine and record the activity of the radiopharmaceutical dosage or radiation dose before medical use.

The following procedures are provided as assistance in meeting the above objectives.

Procedures for Any Therapeutic Dose or Dosage of a Radionuclide or any Dosage of Quantities Greater than 30 Microcurie of Sodium Iodide I-131

Develop, maintain and implement the following procedures to meet the objectives of *12 VAC 5-481-1720* and *12 VAC 5-481-1730*:

- An AU must date and sign a WD prior to the administration of any dose or dosage.
- Prior to administering a dose or dosage, the patient's or human research subject's identity will be positively verified as the individual named in the WD. Examples of positive patient identity verification include examining the patient's ID bracelet, hospital ID card, driver's license, or social security card. Asking or calling the patient's name does not constitute positive patient identity verification.
- The specific details of the administration will be verified, including the dose or dosage, in accordance with the WD or treatment plan. All components of the WD (radionuclide, total dose or dosage, etc.) will be confirmed by the person administering the dose or dosage to verify agreement with the WD. Appropriate verification methods include: measuring the activity in the dose calibrator, checking the serial number of the sealed sources behind an appropriate shield, using color-coded sealed sources, or using clearly marked storage locations.

Additional Procedures for Sealed Therapeutic Sources and Devices Containing Sealed Therapeutic Sources

Licensees are required under *12 VAC 5-481-1720* & *12 VAC 5-481-1730* to have a Written Directive (WD) for certain administrations of doses and to have procedures for administrations for which a WD is required. Procedures for meeting these requirements appear below.

- A. To ensure that the dose is delivered in accordance with the WD, the AU (and the neurosurgeon for GSR therapy) must date and sign (indicating approval of) the treatment plan that provides sufficient information and direction to meet the objectives of the WD.
- B. For sealed sources inserted into the patient's body, radiographs or other comparable images (e.g., computerized tomography) will be used as the basis for verifying the position of the non-radioactive dummy sources and calculating

the administered dose before administration. However, for some brachytherapy procedures, the use of various fixed geometry applicators (e.g., appliances or templates) may be required to establish the location of the temporary sources and to calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary, provided the position of the sources is known prior to insertion of the radioactive sources and calculation of the exposure time (or, equivalently, the total dose).

- C. Dose calculations will be checked before administering the prescribed therapy dose. An AU or a qualified person under the supervision of an AU (e.g., an AMP, oncology physician, dosimetrist, or radiation therapist), preferably one who did not make the original calculations, will check the dose calculations. Methods for checking the calculations include the following:
1. For computer-generated dose calculations, examining the computer printout to verify that correct input data for the patient was used in the calculations (e.g., source strength and positions).
 2. For computer-generated dose calculations entered into the therapy console, verifying correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times).
 3. For manually-generated dose calculations, verifying:
 - a. No arithmetic errors;
 - b. Appropriate transfer of data from the WD, treatment plan, tables and graphs;
 - c. Appropriate use of nomograms (when applicable); and
 - d. Appropriate use of all pertinent data in the calculations.

The therapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer-generated outputs (or vice versa), verify the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual). Parameters such as the transmission factors for wedges and applicators and the source strength of the sealed source used in the dose calculations will be checked.

- D. After implantation but before completion of the procedure: record the written directive the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose) as required by *12 VAC 5-481-1720*. For example, after insertion of permanent implant brachytherapy sources, an AU should promptly record the actual number of radioactive sources implanted and the total source strength. The written directive may be maintained in the patient's chart.
- E. Acceptance testing will be performed by a qualified person (e.g., an AMP) on each treatment planning or dose calculating computer program that could be used for dose calculations. Acceptance testing will be performed before the first use of a treatment planning or dose calculating computer program for therapy dose calculations. Each treatment planning or dose calculating computer program will be assessed based on specific needs and applications. A check of the acceptance testing will also be performed after each source replacement or when spot check measurements indicate that the source output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay.

- F. Independent checks on full calibration measurements will be performed. The independent check will include an output measurement for a single specified set of exposure conditions and will be performed within 30 days following the full calibration measurements. The independent check will be performed by either:
1. An individual who did not perform the full calibration (the individual will meet the requirements specified in *12 VAC 5-481-1760*) using a dosimetry system other than the one that was used during the full calibration (the dosimetry system will meet the requirements specified in *12 VAC 5-481-2040*); or
 2. An AMP (or an oncology physician, dosimetrist, or radiation therapist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming therapy doses and that is accurate within 5%.
- G. For GSR, particular emphasis will be directed on verifying that the stereoscopic frame coordinates on the patient's skull match those of the treatment plan.
- H. A physical measurement of the teletherapy output will be made under applicable conditions prior to administration of the first teletherapy fractional dose, if the patient's treatment plan includes: (1) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration; or (2) transmission factors for beam-modifying devices (except non-recastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration measurement.
- I. A weekly chart check will be performed by a qualified person under the supervision of an AU (e.g., an AMP, dosimetrist, oncology physician, or radiation therapist) to detect mistakes (e.g., arithmetic errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative dose administrations from all treatment fields or in connection with any changes in the WD or treatment plan.
- J. Treatment planning computer systems using removable media to store each patient's treatment parameters for direct transfer to the treatment system will have each card labeled with the corresponding patient's name and identification number. Such media may be reused (and must be relabeled) in accordance with the manufacturer's instructions.

Review of Administrations Requiring a Written Directive

Conduct periodic reviews of each applicable program area, e.g., radiopharmaceutical therapy, high-dose-rate brachytherapy, implant brachytherapy, teletherapy, gamma stereotactic radiosurgery, and emerging technologies. The number of patient cases to be sampled will be based on the principles of statistical acceptance sampling and will represent each treatment modality performed in the institution, e.g., radiopharmaceutical, teletherapy, brachytherapy and gamma stereotactic radiosurgery.

If feasible, the persons conducting the review will not review their own work. If this is not possible, two people will work together as a team to conduct the review of that work. We will regularly review the findings of the periodic reviews to ensure that the procedures for administrations requiring a WD are effective.

As required by *12 VAC 5-481-1730*, a determination will be made as to whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the WD or treatment plan, as applicable. For each patient case reviewed, deviations from the WD, the cause of each deviation, and the action required to prevent recurrence will be identified.

Reports of Medical Events

Notify by telephone VDH no later than the next calendar day after discovery of the medical event and submit a written report to VDH Office within 15 days after the discovery of the medical event, as required by *12 VAC 5-481-2080*. Also notify the referring physician and the patient as required by *12 VAC 5-481-2080*. (**Note:** The telephone number of the VDH Office is (804) 864-8150, daytime; (800) 468-8892 after-hours.)

Appendix T

Procedure for Safe Use of Licensed Material

This procedure provides acceptable methods for safe use of licensed material. You may either adopt this procedure or develop your own procedure to meet the requirements of *12 VAC 5-481-630*, *12 VAC 5-481-720*, *12 VAC 5-481-1850*.

- Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
- Wear disposable gloves at all times while handling radioactive materials.
- Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area using an appropriate survey instrument.
- Use syringe shields for reconstitution of radiopharmaceutical kits and administration of radiopharmaceuticals to patients, except when their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, use other protective methods, such as remote delivery of the dose (e.g., use a butterfly needle.)
- Do not eat, store food, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.
- Wear personnel monitoring devices, if required, at all times while in areas where radioactive materials are used or stored. These devices shall be worn as prescribed by the RSO. When not being worn to monitor occupational exposures, personnel monitoring devices shall be stored in the work place in a designated low-background area.
- Wear extremity dosimeters, if required, when handling radioactive material.
- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
- Never pipette by mouth.
- Wipe-test unsealed radioactive material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate the area.
- Survey with a radiation detection survey meter all areas of licensed material use, including the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate the area. Areas used to prepare and administer therapy quantities of radiopharmaceuticals must be surveyed daily in accordance with *12 VAC 5-481-1860* (except when administering therapy dosages in patients' rooms when patients are confined).
- Store radioactive solutions in shielded containers that are clearly labeled.
- Radiopharmaceutical multi-dose diagnostic and therapy vials must be labeled in accordance with *12 VAC 5-481-1850* and *12 VAC 5-481-880*. Mark the label with the radionuclide, the activity, the date for which the activity is estimated, and the kind of materials (i.e., radiopharmaceutical).
- Syringes and unit dosages must be labeled in accordance with *12 VAC 5-481-1850* and *12 VAC 5-481-880*. Mark the label with the radionuclide, the activity, the date for which the activity is estimated, and the kind of materials (i.e., radiopharmaceutical). If the container is holding less than the quantities listed in *12 VAC 5-481-3750*, the syringe or vial need only be labeled to identify the radioactive drug (*12 VAC 5-481-1850*). To avoid mistaking patient dosages, label the syringe with the type of study and the patient's name.
- For prepared dosages, assay each patient dosage in the dose calibrator (or instrument) before administering it (*12 VAC 5-481-1820*).

- Do not use a dosage if it does not fall within the prescribed dosage range or if it varies more than $\pm 20\%$ from the prescribed dosage, except as approved by an authorized user.
- When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle.
- Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering. If the prescribed dosage requires a written directive, the patient's identity must be verified and the administration must be in accordance with the written directive (*12 VAC 5-481-1730*).
- Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
- Secure all licensed material when not under the constant surveillance and immediate control of the authorized user(s).

Appendix U

Release of Patients or Human Research Subjects Administered Radioactive Materials

Section 12 VAC 5-481-1870, 'Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material,' of 12 VAC 5-481 'Virginia Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts', permits a licensee to "authorize the release from its control any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem)."

In this appendix, the individual or human research subject to whom the radioactive material has been administered is called the "patient."

Release Equation

The activities at which patients could be released were calculated by using, as a starting point, the method discussed in the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, 'Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides.'

NCRP Report No. 37 uses the following equation to calculate the exposure until time t at a distance r from the patient:

Equation U.1:

$$D(t) = \frac{34.6\Gamma Q_0 T_p (1 - e^{-0.693t/T_p})}{r^2}$$

Where:

$D(t)$ = Accumulated exposure at time t , in roentgens

34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44)

Γ = Specific gamma ray constant for a point source, R/mCi-hr at 1 cm

Q_0 = Initial activity of the point source in millicurie, at the time of the release

T_p = Physical half-life in days

r = Distance from the point source to the point of interest, in centimeters

t = Exposure time in days.

This appendix uses the NCRP equation (Equation U.1) in the following manner to calculate the activities at which patients may be released.

- The dose to an individual likely to receive the highest dose from exposure to the patient is taken to be the dose to total decay. Therefore, $(1 - e^{-0.693t/T_p})$ is set equal to 1.
- It is assumed that 1 roentgen is equal to 10 mSv (1 rem).
- The exposure-rate constants and physical half-lives for radionuclides typically used in nuclear medicine and brachytherapy procedures are given in Supplement A to this appendix.

- Default activities at which patients may be released are calculated using the physical half-lives of the radionuclides and do not account for the biological half-lives of the radionuclides.
- When release is based on biological elimination (i.e., the effective half-life) rather than just the physical half-life of the radionuclide, Equation U.1 is modified to account for the uptake and retention of the radionuclide by the patient, as discussed in Supplement B.2.
- For radionuclides with a physical half-life greater than 1 day and no consideration of biological elimination, it is assumed that the individual likely to receive the highest dose from exposure to the patient would receive a dose of 25% of the dose to total decay (0.25 in Equation U.2), at a distance of 1 meter. Selection of 25% of the dose to total decay at 1 meter for estimating the dose is based on measurements discussed in the supporting regulatory analysis that indicate the dose calculated using an occupancy factor, E , of 25% at 1 meter is conservative in most normal situations.
- For radionuclides with a physical half-life less than or equal to 1 day, it is difficult to justify an occupancy factor of 0.25, because relatively long-term averaging of behavior cannot be assumed. Under this situation, occupancy factors from 0.75 to 1.0 may be more appropriate. Thus, for radionuclides with a physical half-life greater than 1 day:

Equation U.2:

$$D(=) = \frac{34.6 \Gamma Q_0 T_p (0.25)}{(100\text{cm})^2}$$

For radionuclides with a physical half-life less than or equal to 1 day, and if an occupancy factor of 1.0 is used:

Equation U.3:

$$D(=) = \frac{34.6 \Gamma Q_0 T_p (1)}{(100 \text{ cm})^2}$$

Equations U.2 and U.3 calculate the dose from external exposure to gamma radiation. These equations do not include the dose from internal intake by household members and members of the public, because the dose from intake by other individuals is expected to be small for most radiopharmaceuticals (less than a few percent), relative to the external gamma dose (see ‘Internal Dose,’ of Supplement B). Further, the equations above do not apply to the dose to breast-feeding infants or children who continue to breast-feed. Patients who are breast-feeding an infant or child must be considered separately, as discussed in **Item U.1.1**, ‘Release of Patients Based on Administered Activity.’

U.1 Release Criteria

Licenseses should use one of the following options to release a patient to whom unsealed radioactive material or implants containing radioactive material have been administered in accordance with regulatory requirements.

U.1.1 Release of Patients Based on Administered Activity

In compliance with the dose limit in *12 VAC 5-481-1870*, licensees may release patients from licensee control if the activity administered is no greater than the activity in Column 1 of **Table 14**. The activities in **Table 14** are based on a total effective dose equivalent of 5 mSv (0.5 rem) to an individual using the following conservative assumptions:

- Administered activity;
- Physical half-life;
- Occupancy factor of 0.25 at 1 meter for physical half-lives greater than 1 day and, to be conservative, an occupancy factor of 1 at 1 meter for physical half-lives less than or equal to 1 day; and
- No shielding by tissue.

The total effective dose equivalent is approximately equal to the external dose because the internal dose is a small fraction of the external dose (see Section B.3, 'Internal Dose,' of Supplement B). In this case, no record of the release of the patient is required unless the patient is breast-feeding an infant or child, as discussed in Item U.3.2, 'Records of Instructions for Breast-Feeding Patients.' The licensee may demonstrate compliance by using the records of activity that are already required by *12 VAC 5-481-1720 & 12 VAC 5-481-1820*.

If the activity administered exceeds the activity in Column 1 of **Table 14**, the licensee may release the patient when the activity has decayed to the activity in Column 1 of **Table 14**. In this case, *12 VAC 5-481-1870* requires a record because the patient's release is based on the retained activity rather than the administered activity. The activities in Column 1 of **Table 14** were calculated using either Equation U.2 or U.3, depending on the physical half-life of the radionuclide.

If a radionuclide that is not listed in **Table 14** is administered, the licensee can demonstrate compliance with the regulation by maintaining, for department inspection, calculation of the release activity that corresponds to the dose limit of 5 mSv (0.5 rem). Equation U.2 or U.3 may be used, as appropriate, to calculate the activity Q corresponding to 5 mSv (0.5 rem).

The release activities in Column 1 of **Table 14** do not include consideration of the dose to a breast-feeding infant or child from ingestion of radiopharmaceuticals contained in the patient's breast milk. When the patient is breast-feeding an infant or child, the activities in Column 1 of **Table 14** are not applicable to the infant or child. In this case, it may be necessary to give instructions as described in **Items U.2.2 and U.2.3** as a condition for release. If failure to interrupt or discontinue could result in a dose to the breast-feeding infant or child in excess of 5 mSv (0.5 rem), a record that instructions were provided is required by *12 VAC 5-481-1870*.

U.1.2 Release of Patients Based on Measured Dose Rate

Licensees may release patients to whom radionuclides have been administered in amounts greater than the activities listed in Column 1 of **Table 14**, provided the measured dose rate at 1 meter (from the surface of the patient) is no greater than the value in Column 2 of **Table 14** for that radionuclide. In this case, however, *12 VAC 5-481-1870* requires a record because the release is based on considering shielding by tissue.

If a radionuclide not listed in **Table 14** is administered and the licensee chooses to release a patient based on the measured dose rate, the licensee should first calculate a dose rate that corresponds to the 5 mSv (0.5 rem) dose limit. If the measured dose rate at 1 meter is no greater than the calculated dose rate, the patient may be released. A record of the release is required by *12 VAC 5-481-1870*. The dose rate at 1 meter may be calculated from Equation U.2 or U.3, as appropriate, because the dose rate at 1 meter is equal to $\Gamma Q/10,000 \text{ cm}^2$.

U.1.3 Release of Patients Based on Patient-Specific Dose Calculations

Licensees may release patients based on dose calculations using patient-specific parameters. With this method, based on *12 VAC 5-481-1870*, the licensee must calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis. If the calculated maximum likely dose to an individual is no greater than 5 mSv (0.5 rem), the patient may be released. Using this method, licensees may be able to release patients with activities greater than those listed in Column 1 of **Table 14** by taking into account the effective half-life of the radioactive material and other factors that may be relevant to the particular case. In this case, a record of the release is required by *12 VAC 5-481-1870*. If the dose calculation considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by *12 VAC 5-481-1870*.

Supplement B contains procedures for performing patient-specific dose calculations, and it describes how various factors may be considered in the calculations.

Table 15 Activities and Dose Rates for Authorizing Patient Release

Radionuclide	COLUMN 1 Activity at or Below Which Patients May Be Released		COLUMN 2 Dose Rate at 1 Meter, at or Below Which Patients May Be Released*	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	19	520	0.08	8
Au-198	3.5	93	0.21	21
Cr-51	4.8	130	0.02	2
Cu-64	8.4	230	0.27	27
Cu-67	14	390	0.22	22
Ga-67	8.7	240	0.18	18
I-123	6.0	160	0.26	26
I-125	0.25	7	0.01	1
I-125 implant	0.33	9	0.01	1
I-131	1.2	33	0.07	7
In-111	2.4	64	0.2	20
Ir-192 implant	0.074	2	0.008	0.8
P-32	**	**	**	**
Pd-103 implant	1.5	40	0.03	3
Re-186	28	770	0.15	15
Re-188	29	790	0.2	20
Sc-47	11	310	0.17	17
Se-75	0.089	2	0.005	0.5
Sm-153	26	700	0.3	30
Sn-117m	1.1	29	0.04	4
Sr-89	**	**	**	**
Tc-99m	28	760	0.58	58
Tl-201	16	430	0.19	19
Y-90	**	**	**	**
Yb-169	0.37	10	0.02	2

Note: The activity values were computed based on 5 mSv (0.5 rem) total effective dose equivalent.

* If the release is based on the dose rate at 1 meter in Column 2, the licensee must maintain a record as required by *12 VAC 5-481-1870*, because the measurement includes shielding by tissue. See Item U.3.1, 'Records of Release,' for information on records.

** Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

Notes: The millicurie values were calculated using Equations U.2 or U.3 and the physical half-life. The gigabecquerel values were calculated using the millicurie values and the conversion factor from millicurie to gigabecquerels. The dose rate values are calculated using the millicurie values and the exposure rate constants.

In general, the values are rounded to two significant figures; however, values less than 0.37 gigabecquerel (10 millicurie) or 0.1 mSv (10 mrem) per hour are rounded to one significant figure. Details of the calculations are provided in NRC *NUREG-1492*.

U.2 Instructions

This Section provides acceptable instructions for release of patients administered radioactive materials. You may either adopt these instructions or develop your own instructions to meet the requirements of *12 VAC 5-481-1870*.

U.2.1 Activities and Dose Rates Requiring Instructions

Based on *12 VAC 5-481-1870*, for some administrations the released patients must be given instructions, including written instructions, on how to maintain doses to other individuals ALARA after the patients are released. (**Note:** VDH does not intend to enforce patient compliance with the instructions nor is it the licensee's responsibility to do so.) Column 1 of **Table 15** provides the activity above which instructions must be given to patients. Column 2 provides corresponding dose rates at 1 meter, based on the activities in Column 1. The activities or dose rates in **Table 15** may be used for determining when instructions must be given. If the patient is breast-feeding an infant or child, additional instructions may be necessary (see Item U.2.2, 'Additional Instructions for Release of Patients Who Could be Breast-Feeding After Release').

When patient-specific calculations (as described in Supplement B) are used, instructions must be provided if the calculation indicates a dose greater than 1 mSv (0.1 rem).

If a radionuclide not listed in **Table 15** is administered, the licensee may calculate the activity or dose rate that corresponds to 1 mSv (0.1 rem). Equation U.2 or U.3, as appropriate, may be used.

U.2.2 Additional Instructions for Release of Patients Who Could Be Breast-Feeding After Release

The requirement in *12 VAC 5-481-1870* that a licensee provide instructions on the discontinuation or the interruption period of breast-feeding, and the consequences of failing to follow the recommendation, presumes that the licensee will inquire, as appropriate, regarding the breast-feeding status of the patient. (**Note:** VDH does not intend to enforce patient compliance with the instructions nor is it the licensee's responsibility to do so.) The purpose of the instructions (e.g., on interruption or discontinuation) is to permit licensees to release a patient who could be breast-feeding an infant or child when the dose to the infant or child could exceed 5 mSv (0.5 rem) if there is no interruption of breast-feeding.

If the patient could be breast-feeding an infant or child after release, and if a radiopharmaceutical with an activity above the value stated in Column 1 of **Table 16** was administered to the patient, the licensee must give the patient instructions on the discontinuation or interruption period for breast-feeding and the consequences of failing to follow the recommendation. The patient should also be informed if there would be no consequences to the breast-feeding infant or child. **Table 16** also provides recommendations for interrupting or discontinuing breast-feeding to minimize the dose to below 1 mSv (0.1 rem) if the patient has received certain radiopharmaceutical doses. The radiopharmaceuticals listed in **Table 16** are commonly used in medical diagnosis and treatment.

If a radiopharmaceutical not listed in **Table 16** is administered to a patient who could be breast-feeding, the licensee should evaluate whether instructions or records (or both) are required. If information on the excretion of the radiopharmaceutical is not available, an acceptable method is to assume that 50% of the administered activity is excreted in the breast milk. The dose to the infant or child can be calculated by using the dose conversion factors given for a newborn infant by Stabin. (**Note:** References are listed following section U.4.)

U.2.3 Content of Instructions

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations; however, the instructions should not interfere with or contradict the best medical judgment of physicians. The instructions may include the name of a knowledgeable contact person and that person's telephone number, in case the patient has any questions. Additional instructions appropriate for each modality, as shown in examples below, may be provided (refer to U.2.3.1 and U.2.3.2).

Table 16 Activities and Dose Rates above Which Instructions Should Be Given When Authorizing Patient Release

Radionuclide	COLUMN 1 Activity Above Which Instructions Are Required		COLUMN 2 Dose Rate at 1 Meter Above Which Instructions Are Required	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	3.8	100	0.02	2
Au-198	0.69	19	0.04	4
Cr-51	0.96	26	0.004	0.4
Cu-64	1.7	45	0.05	5
Cu-67	2.9	77	0.04	4
Ga-67	1.7	47	0.04	4
I-123	1.2	33	0.05	5
I-125	0.05	1	0.002	0.2
I-125 implant	0.074	2	0.002	0.2
I-131	0.24	7	0.02	2
In-111	0.47	13	0.04	4
Ir-192 implant	0.011	0.3	0.002	0.2
P-32	**	**	**	**
Pd-103 implant	0.3	8	0.007	0.7
Re-186	5.7	15.0	0.03	3
Re-188	5.8	160	0.04	4
Sc-47	2.3	62	0.03	3
Se-75	0.018	0.5	0.001	0.1
Sm-153	5.2	140	0.06	6
Sn-117m	0.21	6	0.009	0.9
Sr-89	**	**	**	**
Tc-99m	5.6	150	0.12	12
Tl-201	3.1	85	0.04	4
Y-90	**	**	**	**
Yb-169	0.073	2	0.004	0.4

Note: The activity values were computed based on 1 mSv (0.1 rem) total effective dose equivalent.

** Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

Notes: The millicurie values were calculated using Equations U.2 or U.3 and the physical half-life. The gigabecquerel values were calculated based on millicurie values and the conversion factor from millicurie to gigabecquerels. The dose rate values were calculated based on millicurie values and exposure rate constants.

In general, values are rounded to two significant figures; however, values less than 0.37 gigabecquerel (10 millicurie) or 0.1 mSv (10 mrem) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492.

Table 17 Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who are Breast-Feeding an Infant or Child

Radionuclide	COLUMN 1 Activity Above Which Instructions Are Required		COLUMN 2 Activity Above Which a Record is Required		COLUMN 3 Examples of Recommended Duration of Interruption of Breast-Feeding
	(MBq)	(mCi)	(MBq)	(mCi)	
I-131 NaI	0.01	0.0004	0.07	0.002	Complete cessation (for this infant or child)
I-123 NaI	20	0.5	100	3	
I-123 OIH	100	4	700	20	
I-123 MIBG	70	2	400	10	24 hours for 370 MBq (10 mCi) 12 hours for 150 MBq (4 mCi)
I-125 OIH	3	0.08	10	0.4	
I-131 OIH	10	0.30	60	1.5	
Tc-99m DTPA	1000	30	6000	150	
Tc-99m MAA	50	1.3	200	6.5	12 hours for 150 MBq (4 mCi)
Tc-99m Pertechnetate	100	3	600	15	24 hours for 1,100 MBq (30 mCi) 12 hours for 440 MBq (12 mCi)
Tc-99m DISIDA	1000	30	6000	150	
Tc-99m Glucoheptonate	1000	30	6000	170	
Tc-99m MIBI	1000	30	6000	150	
Tc-99m MDP	1000	30	6000	150	
Tc-99m PYP	900	25	4000	120	
Tc-99m Red Blood Cell <i>In Vivo</i> Labeling	400	10	2000	50	6 hours for 740 MBq (20 mCi)
Tc-99m Red Blood Cell <i>In Vitro</i> Labeling	1000	30	6000	150	
Tc-99m Sulphur Colloid	300	7	1000	35	6 hours for 440 MBq (12 mCi)
Tc-99m DTPA Aerosol	1000	30	6000	150	
Tc-99m MAG3	1000	30	6000	150	
Tc-99m White Blood Cells	100	4	600	15	24 hours for 1,100 MBq (30 mCi) 12 hours for 440 MBq (12 mCi)
Ga-67 Citrate	1	0.04	7	0.2	1 month for 150 MBq (4 mCi) 2 weeks for 50 MBq (1.3 mCi) 1 week for 7 MBq (0.2 mCi)
Cr-51 EDTA	60	1.6	300	8	
In-111 White Blood Cells	10	0.2	40	1	1 week for 20 MBq (0.5 mCi)
Tl-201 Chloride	40	1	200	5	2 weeks for 110 MBq (3 mCi)

* The duration of interruption of breast-feeding is selected to reduce the maximum dose to a newborn infant to less than 1 mSv (0.1 rem), although the regulatory limit is 5 mSv (0.5 rem). The actual doses that would be received by most infants would be

far below 1 mSv (0.1 rem). Of course, the physician may use discretion in the recommendation, increasing or decreasing the duration of interruption.

Notes: Activities are rounded to one significant figure, except when it was considered appropriate to use two significant figures. Details of the calculations are shown in NUREG-1492, 'Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material.'

If there is no recommendation in Column 3 of this table, the maximum activity normally administered is below the activities that require instructions on interruption or discontinuation of breast-feeding.

U.2.3.1 Instructions Regarding Radiopharmaceutical Administrations

For procedures involving radiopharmaceuticals, additional instructions may include the following:

- Maintaining distance from other persons, including separate sleeping arrangements.
- Minimizing time in public places (e.g., public transportation, grocery stores, shopping centers, theaters, restaurants, sporting events).
- Precautions to reduce the spread of radioactive contamination.
- The length of time each of the precautions should be in effect.

The Society of Nuclear Medicine published a pamphlet in 1987 that provides information for patients receiving treatment with radioiodine. The pamphlet contains blanks for the physician to fill in the length of time that each instruction should be followed. Although this pamphlet was written for the release of patients to whom less than 1,110 megabecquerel (30 millicurie) of iodine-131 had been administered, VDH still considers the instructions in this pamphlet to be an acceptable method for meeting the requirements of *12 VAC 5-481-1870*, provided the times filled in the blanks are appropriate for the activity and the medical condition.

If additional instructions are required because the patient is breast-feeding, the instructions should include appropriate recommendations on whether to interrupt breast-feeding, the length of time to interrupt breast-feeding, or, if necessary, the discontinuation of breast-feeding. The instructions should include information on the consequences of failure to follow the recommendation to interrupt or discontinue breast-feeding. The consequences should be explained so that the patient will understand that, in some cases, breast-feeding after an administration of certain radionuclides should be avoided. For example, a consequence of procedures involving iodine-131 is that continued breast-feeding could harm the infant's or child's thyroid. Most diagnostic procedures involve radionuclides other than radioiodine and there would be no consequences; guidance should simply address avoiding any unnecessary radiation exposure to the infant or child from breast-feeding. If the Society of Nuclear Medicine's pamphlet is given at release to a patient who is breast-feeding an infant or child, the pamphlet should be supplemented with information specified in *12 VAC 5-481-1870*.

The requirement of *12 VAC 5-481-1870* regarding written instructions to patients who could be breast-feeding an infant or child does not in any way interfere with the discretion and judgment of the physician in specifying the detailed instructions and recommendations.

U.2.3.2 Instructions Regarding Implants

For patients who have received implants, additional instructions may include the following:

A small radioactive source has been placed (implanted) inside your body. The source is actually many small metallic pellets or seeds, which are each about 1/3 to 1/4 of an inch long, similar in size and shape to a grain of rice. To minimize exposure to radiation to others from the source inside your body, you should do the following for _____ days.

- Stay at a distance of ___ feet from _____.
- Maintain separate sleeping arrangements.
- Minimize time with children and pregnant women.
- Do not hold or cuddle children.
- Avoid public transportation.
- Examine any bandages or linens that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.
- If you find a seed or pellet that falls out:
 - Do not handle it with your fingers. Use something like a spoon or tweezers to place it in a jar or other container that you can close with a lid.
 - Place the container with the seed or pellet in a location away from people.
 - Notify _____ at telephone number _____.

U.3 Records

U.3.1 Records of Release

There is no requirement for recordkeeping on the release of patients who were released in accordance with Column 1 of **Table 14**; however, if the release of the patient is based on a dose calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by *12 VAC 5-481-1870*. This record should include the patient identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radioactive material administered, the administered activity, and the date of the administration. In addition, depending on the basis for release, records should include the following information:

- **For Immediate Release of a Patient Based on a Patient-Specific Calculation:** The equation used, including the patient-specific factors and their bases that were used in calculating the dose to the person exposed to the patient, and the calculated dose. The patient-specific factors (see Supplement B of this appendix) include the effective half-life and uptake fraction for each component of the biokinetic model, the time that the physical half-life was assumed to apply to retention, and the occupancy factor. The basis for selecting each of these values should be included in the record.

- **For Immediate Release of a Patient Based on Measured Dose Rate:** The results of the measurement, the specific survey instrument used, and the name of the individual performing the survey.
- **For Delayed Release of a Patient Based on Radioactive Decay Calculation:** The time of the administration, date and time of release, and the results of the decay calculation.
- **For Delayed Release of a Patient Based on Measured Dose Rate:** The results of the survey meter measurement, the specific survey instrument used, and the name of the individual performing the survey.

In some situations, a calculation may be case-specific for a class of patients who all have the same patient-specific factors. In this case, the record for a particular patient's release may reference the calculation for the class of patients.

Records, as required by *12 VAC 5-481-1870*, should be kept in a manner that ensures the patient's confidentiality, that is, the records should not contain the patient's name or any other information that could lead to identification of the patient. These recordkeeping requirements may also be used to verify that licensees have proper procedures in place for assessing potential third-party exposure associated with and arising from exposure to patients who were administered radioactive material.

U.3.2 Records of Instructions for Breast-Feeding Patients

If failure to interrupt or discontinue breast-feeding could result in a dose to the infant or child in excess of 5 mSv (0.5 rem), a record that instructions were provided is required by *12 VAC 5-481-1870*. Column 2 of **Table 16** states, for the radiopharmaceuticals commonly used in medical diagnosis and treatment, the activities that would require such records when administered to patients who are breast-feeding.

The record should include the patient's identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radiopharmaceutical administered, the administered activity, the date of the administration, and whether instructions were provided to the patient who could be breast-feeding an infant or child.

U.4 Summary Table

Table 17 summarizes the criteria for releasing patients and the requirements for providing instructions and maintaining records.

Table 18 Summary of Release Criteria, Required Instructions to Patients, and Records to be Maintained

Patient Group	Basis for Release	Criteria for Release	Instructions Needed?	Release Records Required?
All patients, including patients who are breast-feeding an infant or child	Administered activity	Administered activity = Column 1 of Table 14	Yes, if administered activity > Column 1 of Table 15	No
	Retained activity	Retained activity = Column 1 of Table 14	Yes, if retained activity > Column 1 of Table 15	Yes
	Measured dose rate	Measured dose rate = Column 2 of Table 14	Yes, if dose rate > Column 2 of Table 15	Yes
	Patient-specific calculations	Calculated dose = 5 mSv (0.5 rem)	Yes, if calculated dose > 1 mSv (0.1 rem)	Yes
Patients who are breast-feeding an infant or child	All of the above bases for release		Additional instructions required if: Administered activity > Column 1 of Table 16 OR Licensee calculated dose from breast-feeding > 1 mSv (0.1 rem) to the infant or child	Records that instructions were provided are required if: Administered activity > Column 2 of Table 17 OR Licensee calculated dose from continued breast-feeding > 5 mSv (0.5 rem) to the infant or child

Implementation

The purpose of this section is to provide information to licensees and applicants regarding VDH staff's plans for using this appendix. Except in those cases in which a licensee proposes an acceptable alternative method for complying with *12 VAC 5-481-1870*, the methods described in this appendix will be used in the evaluation of a licensee's compliance with *12 VAC 5-481-1870*.

References

- National Council on Radiation Protection and Measurements (NCRP), 'Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides,' NCRP Report No. 37, October 1, 1970. (Available for sale from the NCRP, 7910 Woodmont Avenue, Suite 800, Bethesda, MD 20814-3095.)
- S. Schneider and S. A. McGuire, 'Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material,' NUREG-1492 (Final Report), NRC, February 1997.
- M. Stabin, 'Internal Dosimetry in Pediatric Nuclear Medicine,' in *Pediatric Nuclear Medicine*, edited by S. Treves, Springer Verlag, New York, 1995.
- 'Guidelines for Patients Receiving Radioiodine Treatment,' *Society of Nuclear Medicine*, 1987. This pamphlet may be obtained from the Society of Nuclear Medicine, 136 Madison Avenue, New York, NY 10016-6760.

Supplement A

Table 19 Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine

Radionuclide	Physical Half-Life (days) ¹	Exposure Rate Constant ² (R/mCi-h at 1 cm)
Ag-111	7.45	0.150
Au-198	2.696	2.3
Cr-51	27.704	0.16
Cu-64	0.529	1.2
Cu-67	2.578	0.58
F-18	0.076	6.95
Ga-67	3.261	0.753
I-123	0.55	1.61
I-125	60.14	1.42
I-125 implant	60.14	1.11 ³
I-131	8.04	2.2
In-111	2.83	3.21
Ir-192 implant	74.02	4.59 ³
P-32	14.29	NA ⁵
Pd-103 implant	16.96	0.86 ⁴
Re-186	3.777	0.2
Re-188	0.708	0.26
Sc-47	3.351	0.56
Se-75	119.8	2.0
Sm-153	1.946	0.425
Sn-117m	13.61	1.48
Sr-89	50.5	NA ⁵
Tc-99m	0.251	0.756
Tl-201	3.044	0.447
Y-90	2.67	NA ⁵
Yb-169	32.01	1.83

¹ K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, 'Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion,' Report No. EPA-520/1-88-020, Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, DC, 1988.

² Values for the exposure rate constant for Au-198, Cr-51, Cu-64, F-18, I-131, Sc-47, and Se-75 were taken from the *Radiological Health Handbook*, U.S. Department of Health, Education, and Welfare, pp. 135, 1970. For Cu-67, I-123, In-111, Re-186, and Re-188, the values for the exposure rate constant were taken from D.E. Barber, J.W. Baum, and C.B. Meinhold, 'Radiation Safety Issues Related to Radiolabeled Antibodies,' NUREG/CR-4444, U.S. NRC, Washington, DC, 1991. For Ag-111, Ga-67, I-125, Sm-153, Sn-117m, Tc-99m, Tl-201, and Yb-169, the exposure rate constants were calculated because the published values for these radionuclides were an approximation, presented as a range, or varied from one reference to another. Details of the calculation of the exposure rate constants are shown in Table A.2 of Appendix A to NUREG-1492, 'Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material,' U.S. NRC, February 1997.

³ R. Nath, A.S. Meigooni, and J.A. Meli, 'Dosimetry on Transverse Axes of ¹²⁵I and ¹⁹²Ir Interstitial Brachytherapy Sources,' *Medical Physics*, Volume 17, Number 6, November/December 1990. The exposure rate constant given is a measured value averaged for several source models and takes into account the attenuation of gamma rays within the implant capsule itself.

⁴ A.S. Meigooni, S. Sabnis, R. Nath, 'Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants,' *Endocurietherapy Hyperthermia Oncology*, Volume 6, April 1990. The exposure rate constant given is an 'apparent' value (i.e., with respect to an apparent source activity) and takes into account the attenuation of gamma rays within the implant capsule itself.

⁵ Not applicable (NA) because the release activity is not based on beta emission.

Supplement B

Procedures for Calculating Doses Based on Patient-Specific Factors

A licensee may release a patient to whom an activity with a value higher than the values listed in Column 1 of **Table 14** of this supplement has been administered if dose calculations using patient-specific parameters, which are less conservative than the conservative assumptions, show that the potential total effective dose equivalent to any individual would be no greater than 5 mSv (0.5 rem).

If the release of a patient is based on a patient-specific calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, biological or effective half-life, or shielding by tissue, a record of the basis of the release is required by *12 VAC 5-481-1870*. The following equation can be used to calculate doses:

Equation B-1:

$$D(t) = \frac{34.6\Gamma Q_0 TE(1 - e^{-0.693t/T_p})}{r^2}$$

Where:

D(t) = Accumulated dose to time t, in rem;

34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44);

Γ = Exposure rate constant for a point source, R/mCi x hr at 1 cm;

Q_0 = Initial activity at the start of the time interval;

T_p = Physical half-life, in days;

E = Occupancy factor that accounts for different occupancy times and distances when an individual is around a patient;

r = Distance in centimeters. This value is typically 100 cm; and

t = Exposure time in days.

B.1 Occupancy Factor

B.1.1 Rationale for Occupancy Factors Used to Derive Table 14

In **Table 14** in this appendix, the activities at which patients could be released were calculated using the physical half-life of the radionuclide and an occupancy factor at 1 meter of either 0.25 (if the radionuclide has a half-life longer than 1 day) or 1.0 (if the radionuclide has a half-life less than or equal to 1 day). The basis for the occupancy factor of 0.25 at 1 meter is that measurements of doses to family members, as well as considerations of normal human behavior (as discussed in the supporting regulatory analysis (Ref. B-1)), suggest that an occupancy factor of 0.25 at 1 meter, when used in combination with the physical half-life, will produce a generally conservative estimate of the dose to family members when instructions on minimizing doses to others are given.

An occupancy factor of 0.25 at 1 meter is not considered appropriate when the physical half-life is less than or equal to 1 day, and hence, the dose is delivered over a short time. Specifically, the assumptions regarding patient behavior that led to an occupancy factor of 0.25 at 1 meter include the assumption that the patient will not be in close proximity to other individuals for several days; however, when the dose is from a short-lived radionuclide, the time that individuals spend in close proximity to the patient immediately following release will be most significant because the dose to other individuals could be a large fraction of the total dose from the short-lived radionuclide. Thus, to be conservative when providing generally applicable release quantities that may be used with little consideration of the specific details of a particular patient's release, the values calculated in **Table 14** were based on an occupancy factor of 1 at 1 meter when the half-life is less than or equal to 1 day. If information about a particular patient implies the assumptions were to conservative, licensees may consider case specific conditions. Conversely, if young children are present in the household of the patient who is to be discharged, conservative assumptions about occupancy may be appropriate.

B.1.2 Occupancy Factors to Consider for Patient-Specific Calculations

The selection of an occupancy factor for patient-specific calculations will depend on whether the physical or effective half-life of the radionuclide is used and whether instructions are provided to the patient before release. The following occupancy factors, E , at 1 meter, may be used for patient-specific calculations:

- $E = 0.75$ when a physical half-life, an effective half-life, or a specific time period under consideration (e.g., bladder holding time) is less than or equal to 1 day.
- $E = 0.25$ when an effective half-life is greater than 1 day, if the patient has been given instructions, such as:
 - Maintain a prudent distance from others for at least the first 2 days;
 - Sleep alone in a room for at least the first night;
 - Do not travel by airplane or mass transportation for at least the first day;
 - Do not travel on a prolonged automobile trip with others for at least the first 2 days;
 - Have sole use of a bathroom for at least the first 2 days; and
 - Drink plenty of fluids for at least the first 2 days.
- $E = 0.125$ when an effective half-life is greater than 1 day if the patient has been given instructions, such as:
 - Follow the instructions for $E = 0.25$ above;
 - Live alone for at least the first 2 days; and
 - Have few visits by family or friends for at least the first 2 days.
- In a two-component model (e.g., uptake of iodine-131 using thyroidal and extrathyroidal components), if the effective half-life associated with one component is less than or equal to one day but is greater than one day for the other component, it is more justifiable to use the occupancy factor associated with the dominant component for both components.

Example 1:

Calculate the maximum likely dose to an individual exposed to a patient who has received 2,220 megabecquerels (60 millicuries) of iodine-131. The patient received instructions to maintain a prudent distance from others for at least 2 days, lives alone, drives home alone, and stays at home for several days without visitors.

Solution:

The dose to total decay ($t = \infty$) is calculated based on the physical half-life using Equation B-1. (This calculation illustrates the use of physical half-life. To account for biological elimination, calculations described in the next section should be used.)

$$D(\infty) = \frac{34.6 \Gamma Q_0 T_p E}{r^2}$$

Because the patient has received instructions for reducing exposure as recommended for an occupancy factor of $E = 0.125$, the occupancy factor of 0.125 at 1 meter may be used.

$$D(\infty) = \frac{34.6(2.2R \cdot \text{cm}^2 / \text{mCi} \cdot \text{hr})(60\text{mCi})(8.04\text{d})(0.125)}{(100 \text{ cm})^2}$$

$$D(\infty) = 4.59 \text{ mSv (0.459 rem)}$$

Since the dose is less than 5 mSv (0.5 rem), the patient may be released, but *12 VAC 5-481-1870* requires that instructions be given to the patient on maintaining doses to others as low as is reasonably achievable. A record of the calculation must be maintained, pursuant to *12 VAC 5-481-1870*, because an occupancy factor of less than 0.25 at 1 meter was used.

B.2 Effective Half-Life

A licensee may take into account the effective half-life of the radioactive material to demonstrate compliance with the dose limits for individuals exposed to the patient that are stated in *12 VAC 5-481-1870*. The effective half-life is defined as:

Equation B-2:

$$T_{eff} = \frac{T_b \times T_p}{T_b + T_p}$$

Where:

T_b = Biological half-life of the radionuclide and

T_p = Physical half-life of the radionuclide.

The behavior of iodine-131 can be modeled using two components: extrathyroidal iodide (i.e., existing outside of the thyroid) and thyroidal iodide following uptake by the thyroid. The effective half-lives for the extrathyroidal and thyroidal fractions (i.e., F_1 and F_2 , respectively) can be calculated with the following equations.

Equation B-3:

$$T_{1eff} = \frac{T_{b1} \times T_p}{T_{b1} + T_p}$$

Equation B-4:

$$T_{2eff} = \frac{T_{b2} \times T_p}{T_{b2} + T_p}$$

Where:

T_{b1} = Biological half-life for extrathyroidal iodide;

T_{b2} = Biological half-life of iodide following uptake by the thyroid; and

T_p = Physical half-life of iodine-131.

However, simple exponential excretion models do not account for: (a) the time for the iodine-131 to be absorbed from the stomach to the blood; and (b) the holdup of iodine in the urine while in the bladder. Failure to account for these factors could result in an underestimate of the dose to another individual. Therefore, this supplement makes a conservative approximation to account for these factors by assuming that, during the first 8 hours after the administration, about 80% of the iodine administered is removed from the body at a rate determined only by the physical half-life of iodine-131.

Thus, an equation to calculate the dose from a patient administered iodine-131 may have three components. First is the dose for the first 8 hours (0.33 day) after administration. This component comes directly from Equation B-1, using the physical half-life and a factor of 80%. Second is the dose from the extrathyroidal component from 8 hours to total decay. In this component, the first exponential factor represents the activity at $t = 8$ hours based on the physical half-life of iodine-131. The second exponential factor represents the activity from $t = 8$ hours to total decay based on the effective half-life of the extrathyroidal component. The third component, the dose from the thyroidal component for 8 hours to total decay, is calculated in the same manner as the second component. The full equation is shown as Equation B-5.

Equation B-5:

$$D(\infty) = \frac{34.6 \Gamma Q_0}{(100 \text{ cm})^2} \{ E_1 T_p (0.8) (1 - e^{-0.693(0.33)/T_p}) + e^{-0.693(0.33)/T_p} E_2 F_1 T_{1eff} + e^{-0.693(0.33)/T_p} E_2 F_2 T_{2eff} \}$$

Where:

F_1 = Extrathyroidal uptake fraction;

F_2 = Thyroidal uptake fraction;

E_1 = Occupancy factor for the first 8 hours; and

E_2 = Occupancy factor from 8 hours to total decay.

All the other parameters are as defined in Equations B-1, B-3, and B-4. Acceptable values for F_1 , $T_{1\text{eff}}$, F_2 , and $T_{2\text{eff}}$ are shown in **Table 19** for thyroid ablation and treatment of thyroid remnants after surgical removal of the thyroid for thyroid cancer. If these values have been measured for a specific individual, the measured values may be used.

The record of the patient's release required by *12 VAC 5-481-1870* is described in Item U.3.1 of this appendix.

Example 2, Thyroid Cancer:

Calculate the maximum likely dose to an individual exposed to a patient to whom 5550 megabecquerel (150 millicurie) of iodine-131 have been administered for the treatment of thyroid remnants and metastasis.

Solution:

In this example, we will calculate the dose by using Equation B-5 to account for the elimination of iodine-131 from the body, based on the effective half-lives appropriate for thyroid cancer. The physical half-life and the exposure rate constant are from **Table 18**. The uptake fractions and effective half-lives are from **Table 19**. An occupancy factor, E , of 0.75 at 1 meter, will be used for the first component because the time period under consideration is less than 1 day; however, for the second and third components, an occupancy factor of 0.25 will be used, because: (1) the effective half-life associated with the dominant component is greater than 1 day; and (2) patient-specific questions were provided to the patient to justify the occupancy factor (see Section B.1.2, 'Occupancy Factors to Consider for patient-Specific Calculations,' of this Supplement).

Substituting the appropriate values into Equation B-5, the dose to total decay is:

$$D(\infty) = \frac{(34.6)(2.2)(150)}{(100 \text{ cm})^2} \{ (0.75)(8.04)(0.8)(1 - e^{-0.693(0.33)/8.04}) + e^{-0.693(0.33)/8.04} (0.25)(0.95)(0.32) + e^{-0.693(0.33)/8.04} (0.25)(0.95)(7.3) \}$$

$$D(\infty) = 3.40 \text{ mSv (0.340 rem)}$$

Table 20 Uptake Fractions and Effective Half-Lives for Iodine-131 Treatments

Medical Condition	Extrathyroidal Component		Thyroidal Component	
	Uptake Fraction F_1	Effective Half-Life $T_{1\text{eff}}$ (day)	Uptake Fraction F_2	Effective Half-Life $T_{2\text{eff}}$ (day)
Hyperthyroidism	0.20 ¹	0.32 ²	0.80 ¹	5.2 ¹
Post Thyroidectomy for Thyroid Cancer	0.95 ³	0.32 ²	0.05 ³	7.3 ²

- 1 M.G. Stabin et al., 'Radiation Dosimetry for the Adult Female and Fetus from Iodine-131 Administration in Hyperthyroidism,' *Journal of Nuclear Medicine*, Volume 32, Number 5, May 1991. The thyroid uptake fraction of 0.80 was selected as one that is seldom exceeded by the data shown in Figure 1 in this referenced document. The effective half-life of 5.2 days for the thyroidal component was derived from a biological half-life of 15 days, which was obtained from a straight-line fit that accounts for about 75% of the data points shown in Figure 1 of the *Journal of Nuclear Medicine* document.
- 2 International Commission on Radiological Protection (ICRP), 'Radiation Dose to Patients from Radiopharmaceuticals,' ICRP Publication No. 53, March 1987. (Available for sale from Pergamon Press, Inc., Elmsford, NY 10523.) The data in that document suggest that the extrathyroidal component effective half-life in normal subjects is about 0.32 days. Lacking other data, this value is applied to hyperthyroid and thyroid cancer patients. For thyroid cancer, the thyroidal component effective half-life of 7.3 days is based on a biological half-life of 80 days (adult thyroid), as suggested in the ICRP document.
- 3 The thyroidal uptake fraction of 0.05 was recommended by M. Pollycove, M.D., NRC medical visiting fellow, as an upper-limit post-thyroidectomy for thyroid cancer.

Therefore, thyroid cancer patients to whom 5550 megabecquerel (150 millicurie) of iodine-131 or less has been administered would not have to remain under licensee control and could be released under *12 VAC 5-481-1870*, assuming that the foregoing assumptions can be justified for the individual patient's case and that the patient is given instructions. Patients administered somewhat larger activities could also be released immediately if the dose is not greater than 5 mSv (0.5 rem).

In the example above, the thyroidal fraction, $F_2 = 0.05$, is a conservative assumption for persons who have had surgery to remove thyroidal tissue. If F_2 has been measured for a specific patient, the measured value may be used.

Example 3, Hyperthyroidism:

Calculate the maximum likely dose to an individual exposed to a patient to whom 2035 megabecquerel (55 millicurie) of iodine-131 has been administered for the treatment of hyperthyroidism (i.e., thyroid ablation).

Solution:

In this example, we will again calculate the dose using Equation B-5, **Table 18**, and **Table 19**, to account for the elimination of iodine-131 from the body by using the effective half-lives appropriate for hyperthyroidism. An occupancy factor, E , of 0.25 at 1 meter will be used for the second and third components of the equation because patient-specific

instructions were provided to justify the occupancy factor (see Section B.1.2, 'Occupancy Factors to Consider for Patient-Specific Calculations').

Substituting the appropriate values into Equation B-5, the dose to total decay is:

$$D(\infty) = \frac{(34.6)(2.2)(55)}{(100 \text{ cm})^2} \left\{ (0.75)(8.04)(0.8) (1 - e^{-0.693(0.33)/8.04}) \right. \\ \left. + e^{-0.693(0.33)/8.04} (0.25)(0.20)(0.32) + e^{-0.693(0.33)/8.04} (0.25)(0.80)(5.2) \right\}$$

$$D(\infty) = 4.86 \text{ mSv (0.486 rem)}$$

Therefore, hyperthyroid patients to whom 2035 megabecquerels (55 millicuries) of iodine-131 have been administered would not have to remain under licensee control and could be released under *12 VAC 5-481-1870* when the occupancy factor of 0.25 in the second and third components of the equation is justified.

In the example above, the thyroidal fraction $F_2 = 0.8$ is a conservative assumption for persons who have this treatment for hyperthyroidism. If F_2 has been measured for a specific patient, the measured value may be used.

B.3 Internal Dose

For some radionuclides, such as iodine-131, there may be concerns that the internal dose of an individual from exposure to a released patient could be significant. A rough estimate of the maximum likely committed effective dose equivalent from internal exposure can be calculated from Equation B-6.

Equation B-6:

$$D_i = Q (10^{-5})(DCF)$$

Where:

D_i = Maximum likely internal committed effective dose equivalent to the individual exposed to the patient in rem;

Q = Activity administered to the patient in millicurie;

10^{-5} = Assumed fractional intake; and

DCF = Dose conversion factor to convert an intake in millicurie to an internal committed effective dose equivalent (such as tabulated in Reference B-2).

Equation B-6 uses a value of 10^{-5} as the fraction of the activity administered to the patient that would be taken in by the individual exposed to the patient. A common rule of thumb is to assume that no more than 1 millionth of the activity being handled will become an intake to an individual working with the material. This rule of thumb was developed in reference B-3 for cases of worker intakes during normal workplace operations, worker intakes from accidental exposures, and public intakes from accidental airborne releases from a facility, but it does not specifically apply to cases of intake by an

individual exposed to a patient. However, two studies (Refs. B-4 and B-5) regarding the intakes of individuals exposed to patients administered iodine-131, indicated that intakes were generally of the order of 1 millionth of the activity administered to the patient and that internal doses were far below external doses. To account for the most highly exposed individual and to add a degree of conservatism to the calculations, a fractional transfer of 10^{-5} has been assumed.

Example 4, Internal Dose:

Using the ingestion pathway, calculate the maximum internal dose to a person exposed to a patient to whom 1221 megabecquerels (33 millicuries) of iodine-131 have been administered. The ingestion pathway was selected because it is likely that most of the intake would be through the mouth or through the skin, which is most closely approximated by the ingestion pathway.

Solution:

This is an example of the use of Equation B-6. The dose conversion factor DCF for the ingestion pathway is 53 rem/millicurie from Table 2.2 of Reference B-2.

Substituting the appropriate values into Equation B-6, the maximum internal dose to the person is:

$$D_i = (33 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$

$$D_i = 0.17 \text{ mSv (0.017 rem)}$$

Using Equation B-1 and assuming the patient has received instruction for reducing exposure as recommended for an occupancy factor of 0.25, the external dose is approximately 5 mSv (0.5 rem). Thus, the internal dose is about 3% of the external gamma dose. Internal doses may be ignored in the calculations if they are likely to be less than 10% of the external dose, because the internal dose would be significantly less than the uncertainty in the external dose.

The conclusion that internal contamination is relatively unimportant in the case of patient release was also reached by the NCRP. The NCRP addressed the risk of intake of radionuclides from patients' secretions and excreta in NCRP Commentary No. 11, 'Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients' (Ref. B-6). The NCRP concluded, "Thus, a contamination incident that could lead to a significant intake of radioactive material is very unlikely." For additional discussion on the subject, see Reference B-1.

Example 5, Internal Dose:

Calculate the maximum internal dose to a person exposed to a patient to whom 5550 megabecquerel (150 millicurie) of iodine-131 has been administered for the treatment of thyroid remnants and metastasis.

Solution:

In this example, we will again calculate the dose using Equation B-6 and selecting the ingestion pathway. Substituting the appropriate values into Equation B-6, the maximum internal dose to the person is:

$$D_i = (150 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$

$$D_i = 0.80 \text{ mSv (0.08 rem)}$$

In this case, the external dose to the other person from Example 2, Thyroid Cancer, was approximately 3.4 mSv (0.34 rem), while the internal dose would be about 0.80 mSv (0.08 rem). Thus, the internal dose is about 24% of the external gamma dose. Therefore, the internal and external doses must be summed to determine the total dose; 4.2 mSv (0.42 rem).

References for Supplement B

- B-1. S. Schneider and S.A. McGuire, 'Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material,' U.S. NRC, NUREG-1492, February 1997.
- B-2. K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, 'Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion,' Federal Guidance Report No.11, U. S. Environmental Protection Agency, Washington, DC, 1988.
- B-3. A. Brodsky, 'Resuspension Factors and Probabilities of Intake of Material in Process (or 'Is 10^{-6} a Magic Number in Health Physics?'),' *Health Physics*, Volume 39, Number 6, 1980.
- B-4. R.C.T. Buchanan and J.M. Brindle, 'Radioiodine Therapy to Out-patients – The Contamination Hazard,' *British Journal of Radiology*, Volume 43, 1970.
- B-5. A.P. Jacobson, P.A. Plato, and D. Toeroek, 'Contamination of the Home Environment by Patients Treated with Iodine-131,' *American Journal of Public Health*, Volume 68, Number 3, 1978.
- B-6. National Council on Radiation Protection and Measurements, 'Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients,' Commentary No. 11, February 28, 1995.

Regulatory Analysis

'Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material' (NUREG-1492, February 1997) provides the regulatory basis and examines the costs and benefits. A copy of NUREG-1492 is available for inspection and copying for a fee at NRC's Public Document Room, 2120 L Street NW, Washington, DC. Copies may be purchased at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202)512-2249), or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161.

Appendix V

Guidance for Mobile Medical Services

Mobile medical service providers must comply with all applicable sections of **12 VAC 5-481 ‘Virginia Radiation Protection Regulations’, Part VII ‘Use of Radionuclides in the Healing Arts’** as well as DOT regulations with regard to approved source holders, placement of sources in approved containers prior to their transport, and hazardous materials training. For example, mobile medical service providers offering remote afterloaders must comply with **12 VAC 5-481-2040**.

Type and Location of Use

In general, there are two types of mobile medical service. One type is to transport and use radioactive material within a transport vehicle (e.g., in-coach/van use). A second type is to transport radioactive material to a client’s facility and use within a client’s facility by the mobile medical service’s employees.

For the first and second types, which include material use by the service provider, the service provider must apply for full service authorization. Service providers who only transport and store a therapy device need only apply for authorization for possession and transportation of the radioactive material. In this case, when the service provider is only transporting the therapy device for use, the client must possess a license for medical use of the radioactive material. Additionally, in this case, the client is authorized to provide the patient treatments and is responsible for all aspects of the radioactive material use and patient treatments upon transfer of the radioactive material to their possession.

For all types, licensed activities must be conducted in accordance with the rules for compliance with **12 VAC 5-481-1880**, which states that the licensee will obtain a letter signed by the management (i.e., chief executive officer or delegate) of each of its clients for which services are rendered. The letter will permit the use of radioactive material at the client’s address and will clearly delineate the authority and responsibility of each entity. This agreement must be applicable for the entire period of time over which the service is to be provided. The letter will be retained for 3 years after the last provision of service, as required by **12 VAC 5-481-1880** and **12 VAC 5-481-2070**. Additionally, as required by **12 VAC 5-481-1880**, the licensee will survey to ensure compliance with the requirements in **12 VAC 5-481 ‘Virginia Radiation Protection Regulations’, Part IV ‘Standards for Protection Against Radiation’** (e.g., ensure that all radioactive material, including radiopharmaceuticals, sealed sources, and all associated wastes have been removed) before leaving a client’s address.

The location of use for mobile medical services is of two basic types. One type of location is the base location where licensed material is received, stored, and sometimes used. The other type of location is the temporary job site at client facilities. The following section describes the required information necessary for base locations and temporary job sites.

Base Location and Client Site(s)

The base location (e.g., the central radiopharmaceutical laboratory or the storage location for the remote afterloader) for the mobile medical service must be specified. The base facility may be located in a medical institution, non-institutional

medical practice, commercial facility, or the mobile coach/van. You must specify in what type of facility the proposed base facility is located. A mobile licensee cannot provide a service to a private practice (non-licensee) located within a licensed medical institution (e.g., hospital). As required by *12 VAC 5-481-450* and *12 VAC 5-481-440*, you must submit a detailed description and diagram(s) of the proposed base facility and associated equipment in accordance with **Items 8.1 through 8.5** of this VAREG. The description and diagram of the proposed facility must demonstrate that the building (or coach/van) is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), ensures security of licensed material to prevent unauthorized access (e.g., control of keys), and ensures that radiation levels in unrestricted areas are in compliance with *12 VAC 5-481-720*. Include a diagram showing the location of the licensed material, receipt, and use areas, and identify all areas adjacent to restricted areas, including areas above and below the restricted areas. For storage locations within the coach/van, the description of the coach/van must address radiation levels in the driver's compartment to demonstrate compliance with *12 VAC 5-481-640*, '*Occupational dose limits for adults.*'

- You may request multiple base locations. Radioactive material must be delivered only to a facility licensed to receive the type of radioactive material ordered.
- Base locations can include the use of a mobile coach/van. When the base facility is in the coach/van, and there is no permanent structure for the radioactive material storage, the service must provide for the following:
 - Secured off-street parking under licensee control. Public rights-of-way are not considered part of the address of the client;
 - Secured storage facilities available for storage of radioactive material and radioactive waste if the coach/van is disabled; and
 - Radioactive material can be delivered directly to the coach/van only if the coach/van is occupied by licensee's personnel at the time of delivery.
- If a base facility is located in a residential area, the following information must be provided:
 - Justification of the need for a private residence location rather than for a commercial location.
 - Documentation of the agreement between the residence owner and the licensee. It is essential that the mobile medical service have access to the facility in the event of contamination. Provisions for decontamination of the mobile medical service coach/van, etc., on the client property (if necessary) will be included. Documentation from both parties will illustrate the agreement between the client and the mobile medical service.
 - A description of the program demonstrating compliance with *12 VAC 5-481-720*, '*Dose limits for individual members of the public.*'
 - Verification that restricted areas does not contain residential quarters.
- Perform surveys necessary to show that the exposure rate does not exceed 2 mrem in any one hour or TEDE does not exceed 100 mrem per year. Restrict access to members of the public if these limits can not be met (e.g., cones, ropes and signs).

If you will provide transportable services to the client's site for use within the client's facility by the mobile medical service's employees, you must provide the following client facility information and commitment:

- A detailed description and diagram(s) of the proposed use facility (e.g., client site) and associated equipment in accordance with **Items 8.1 through 8.5** of this VAREG. The description and diagram of the proposed use facility must demonstrate that the facility is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), ensure security of licensed material to prevent unauthorized access, and ensure that radiation levels in unrestricted areas are in compliance with *12 VAC 5-481-720*. You must include a diagram showing the location of the equipment, receipt, and use areas, and identify all areas adjacent to restricted areas.
- A commitment, as delineated in the letter required by *12 VAC 5-481-1880*, that the mobile medical service licensee has full control of the treatment room during radioactive material use for each client.
- *12 VAC 5-481-1880* prohibits radioactive material from being delivered directly to a non-licensed client site when mobile medical staff are not present. If the mobile service provider wishes to have radioactive material delivered when staff is not present, provide the following information:
 - Commitment from client that radioactive material will be secured from unauthorized access;
 - Diagram of storage location if separate from use location;

Mobile Therapy Services

This section applies only to therapeutic uses of radioactive material. For all types of therapy uses, the medical institutions, hospitals, or clinics and their addresses that comprise the client sites for mobile medical services must be listed.

For self-contained radioactive material services (e.g., in-coach/van) you must provide the following additional facility information:

- For therapy treatments with radioactive material (e.g., high dose-rate remote afterloader), a separate drawing for each client site showing the location of the treatment device/vehicle in relation to all nearby roads, sidewalks, structures, and any other locations accessible by members of the public;
- A signed agreement, as delineated in the letter required by *12 VAC 5-481-1880*, that the location of the device/vehicle will be on client-owned or controlled property;
- The protection from vehicular traffic that could adversely affect patient treatment(s), that could be accomplished either by locating the facility away from all vehicular traffic or by using barriers. Any protective measures must be shown on the facility/site drawings provided.
- A description of the emergency lighting system that automatically activates on detection of the loss of primary power during patient remote afterloader treatments. The system must provide sufficient light to perform any possible emergency procedures, including the removal of a detached or stuck source that remains within the patient.

- If you will provide transportable services to the client's site for use within the client's facility by the mobile medical service's employees, you must provide the initial installation records and function checks of a remote afterloader device for each site of use, as required by [*12 VAC 5-481-2040*].

For a transport-only mobile medical service for therapy devices that are transported to the client's facility, used by the client's staff (under their own license), and removed by the service provider, you must ensure the following:

- Each client is properly licensed for medical use of radioactive material. If applicable, you must ensure that each client has received the necessary initial and recurrent training for the specific make and model of the remote afterloader device being provided. If the above applicable conditions are not met, the mobile medical service licensee must not transfer the remote afterloader device to the client.
- No signed agreement with a client may state or imply any assumption of responsibility on the part of the mobile medical service for the use of radioactive material for patient treatments. This includes such activities as dosage measurements, source calibrations, and remote afterloader device operational checks. Although these and other services may be provided to the client by the mobile medical service if the mobile medical service is specifically licensed to provide such services, the client (licensee) retains all of the responsibilities related to the use of the radioactive material for patient treatments. The responsibilities for supervising individuals who use the radioactive material, set forth in *12 VAC 5-481-1710*, transfer to the client's Authorized Users (AUs) upon transfer of the device to the client by the mobile medical service provider.
- The initial installation of a remote afterloader device at the client site may be performed by either the mobile medical service provider or the client, but all device function checks are the responsibility of the client (i.e., the licensee authorized to provide patient treatments at the client site).
- As required by *12 VAC 5-481-100*, a formal record of the transfer of control of the radioactive material from the mobile medical service provider to the client, and from the client back to the mobile medical service provider, must be made for each transfer of radioactive material. A signed receipt of each transfer must be made and retained for inspection for 3 years.

Supervision

You must have an authorized user designated to supervise mobile medical staff for each location of use. The supervising authorized user must commit to periodically observe supervised individual(s) or you must provide an alternate method to ensure that the supervised individual(s) follows policies and procedures.

In addition to the requirements in *12 VAC 5-481-2270*, you will instruct supervised individuals in your written radiation protection procedures, written directive procedures, department rules, and license conditions with respect to the use of radioactive material. Additionally, you will require the supervised individual to:

- Follow the instructions of the supervising authorized user for medical uses of radioactive material;

- Follow the instructions of the supervising authorized nuclear pharmacists or supervising authorized user for preparation of radioactive material for medical uses.
- Follow the written radiation protection procedures and written directive procedures established by the licensee.

You may add new supervising individual(s) at a client location. You must notify VDH within 30 days of adding the new supervising individual(s) per *12 VAC 5-481-1690*. This notification does not require a fee.

Training for Individuals Working in or Frequenting Restricted Areas

Drivers and technologists (or therapists) will be properly trained in applicable transportation regulations and emergency procedures in addition to the training requirements of [*12 VAC 5-481-2270, 12 VAC 5-481-1960, 12 VAC 5-481-2010, 12 VAC 5-481-2040*] (as applicable). The training for these individuals will include, at a minimum, DOT regulations (see **Item 9.19** and **Appendix W**), shielding, ALARA, and basic radiation protection.

Survey Instrument and Dose Measurement Instrument Checks

As required by *12 VAC 5-481-1880*, you will check survey instruments for proper operation with a dedicated check source before use at each address of use. You will check dose measurement instruments before medical use at each address of use or on each day of use, whichever is more frequent. Additionally, all other transported equipment (e.g., cameras) should be checked for proper function before medical use at each address of use.

Order and Receipt of Radioactive Material

A supplier will deliver radioactive material to the base location or to the client's address if the client is licensed to receive the type of radioactive material ordered. You may request an exception for a dedicated location of use within a non-licensed client's facility. Delivery of radioactive material to a coach/van that is not occupied by the mobile medical service personnel is prohibited. Alternatively, you may pick up the radioactive material (e.g., radiopharmaceuticals) from the supplier (e.g., nuclear pharmacy) en route to client facilities.

Emergency Procedures

Develop, implement, and maintain emergency procedures, in accordance with your radiation protection program required by *12 VAC 5-481-630*. You should indicate typical response times of the RSO and AU in the event of an incident and develop and implement procedures that include emergency response regarding an accident scenario. An accident is defined as a vehicle collision or other event, such as, wind, water, or fire that results in damage to exterior or interior portions of the vehicle or the radioactive material used in the mobile medical service. The transportation emergency response plan should cover both the actions to be taken by the mobile medical service provider's headquarters emergency

response personnel and the “on-scene” hazardous material-trained personnel, and it will be readily available to both transport vehicle personnel and headquarters emergency-response contacts. The plan should include the following:

- A 24-hour emergency contact telephone number for the mobile medical service provider’s emergency response personnel.
- The emergency contact numbers for the Virginia Department of Health / Radioactive Materials Program. (During office hours: 7:45 a.m. to 4:30 p.m. (804) 864-8150; After hours (800) 468-8892)
- Procedures for restricting access to the transport vehicle until surveys have been made to determine if any radiological hazards exist.
- Procedures for retrieving and securing any radioactive material, including a sealed source that may become detached and/or dislodged to the extent that a radiological hazard is created, which may require one or more emergency shielded source containers.
- Predetermined (calculated) exposure rates for an unshielded therapy source (if applicable) as a function of distance for use in controlling the exposures of emergency response personnel to the maximum extent possible under various emergency response scenarios.
- Preplanned decontamination procedures, including ready access to all necessary materials.
- A calibrated, operational survey meter maintained in the cab of the transporting vehicle, which may be used at an accident scene for conducting surveys.
- Security of the transport vehicle against unauthorized access, including the driver’s compartment.
- Procedures to ensure that following any accident, no patient treatments with remote afterloaders will occur until all systems pertaining to radiation safety have been tested and confirmed to be operational by the RSO or an AMP. If any problem is found, including remote afterloader device interlocks and operation, the remote afterloader device or facility will be repaired and re-certified by the device vendor prior to return to service. In addition, a copy of the report, generated in accordance with *12 VAC 5-481-1100*, will be provided to clients following any accident in which there is actual or possible damage to the client’s facility or the device.

Note: The type of response should be consistent with the level of the incident. The response may range from phone contact for minor spills to prompt on-site response (less than 3 hours) to events such as a medical event or lost radioactive material.

Transportation

Develop, document, and implement procedures to assure that the following take place:

- Radioactive material is transported in accordance with DOT *49 CFR Parts 170–189*. Procedures will include:
 - Use of approved packages;
 - Use of approved labeling;
 - Conduct of proper surveys;
 - Complete and accurate shipping papers;

- Bracing of packages;
 - Security provisions; and
 - Written emergency instructions.
- Management (or management's designee) will perform audits, at least annually, of transportation documentation (e.g., shipping papers and survey reports) and activities at client facilities.
 - Licensed material is secured during transport and use at the client's facilities.
 - Radioactive waste is handled properly during transport. You will describe the method of storage and final disposal.
 - The transport vehicle, including the driver's compartment, if separate, will be secured at all times from any unauthorized access when the vehicle is unattended.

Note: The necessary DOT Type 7A package certification for remote afterloader devices is established by prior approval of the appropriate sealed source and device sheets. However, if the remote afterloader device is damaged in any way during use or transport, then the integrity of the DOT Type 7A packaging may be compromised. The device must not be used or transported until checked by the vendor and certified as retaining its integrity as a Type 7A package.

Radioactive Waste Management

If waste will be stored in coach/vans, the vehicle will be properly secured and posted as radioactive material storage locations. You will ensure that the coach/van will be secured against unauthorized access and that the waste storage location will be posted as a radioactive material storage area.

Develop, document, and implement final waste disposal procedures in accordance with **Item 10** of this guide.

Excreta from individuals undergoing medical diagnosis or therapy with radioactive material may be disposed of without regard to radioactivity if it is discharged into the sanitary sewerage system, in accordance with **12 VAC 5-481-930**.

However, collecting excreta from patients in a coach/van restroom with a holding tank is not considered direct disposal into the sanitary sewerage system.

If a restroom facility is provided in the coach/van for patient use, submit the following information for department review:

- A description of the structure of the tank holding facility and the location of the tank in relation to members of the public, workers in the coach/van, and the driver of the coach/van; a description of procedures to assess the tank for possible leakage and a description of any restroom ventilation if any I-131 will be held in the tank.
- A description of procedures to ensure doses to occupational workers and members of the public will not exceed the exposure limits in **12 VAC 5-481-640** and **12 VAC 5-481-720**, that the external surfaces of the coach/van do not exceed 2 mrem/hour, and that doses to members of the public and workers are maintained

ALARA, including considerations of external dose rates in the restroom caused by the proximity of the holding tank to the toilet.

- A description of procedures for emptying and disposing of the contents of the holding tank, including the frequency of disposal, who empties the tank into the sanitary sewer system, and the location of disposal into the sanitary sewer, including precautions taken to minimize contamination in this process.

Mobile Medical Services With Remote Afterloader Devices

Because the movement of the remote afterloader device from one location to another increases the risk of electro-mechanical component failures or misalignments, it is important that proper operation of the device be fully checked after each such relocation. Therefore, develop, document, and implement the following procedures to determine if a device is operating properly before the commencement of patient treatments:

- Safety checks conducted on a remote afterloader device and facility. The procedure must include the periodic spot checks required by *12 VAC 5-481-2040* and the additional spot checks required by *12 VAC 5-481-2040* before use at each address of use. Additionally, the procedure should include provisions for prompt repair of any system not operating properly.
- The pretreatment operational function checks after each device move should include a review of any device alarm or error message and, if necessary, a resolution of problems indicated by such messages.
- Such tests should be performed in accordance with written procedures.
- You must maintain records, as described in *12 VAC 5-481-2070*, showing the results of the above safety checks for VDH inspection and review for a period of 3 years.
- Perform surveys of the source housing and areas adjacent to the treatment room following relocation of a HDR unit. These surveys should include the source housing with the source in the shielded position and all areas adjacent to the treatment room with the source in the treatment position.

Appendix W

Summary of DOT Requirements for Transportation of Type A or Type B Quantities of Licensed Material

Licensed material must be transported in accordance with DOT regulations. The major areas in the DOT regulations that are most relevant for transportation of Type A or Type B quantities of licensed material are:

- Table of Hazardous Materials and Special Provisions **49 CFR 172.101**: Hazardous materials table, list of hazardous substances, and reportable quantities;
- Shipping Papers **49 CFR 172.200-204**: Applicability, general entries, description of hazardous material on shipping papers, 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**: Applicability, general marking requirements for non-bulk packagings, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging;
- Package Labeling **49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440**: General labeling requirements, prohibited labeling, Class 7 (radioactive) material, placement of labels, label specifications, radioactive white-I label, radioactive yellow-II label, radioactive yellow-III label;
- 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 of placarding requirements, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, general specifications for placards, RADIOACTIVE placard;
- Emergency Response Information **49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604**: Applicability and general requirements, emergency response information, emergency response telephone number;
- Training **49 CFR 172.702, 49 CFR 172.704**: Applicability and responsibility for training and testing, training requirements;
- Security Plans **49 CFR 172.800, 49 CFR 172.802**: Purpose and applicability, components of a security plan;
- Shippers – General Requirements for Shipments and Packaging **49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.411, 49 CFR 173.412, 49 CFR 173.413, 49 CFR 173.415, 49 CFR 173.416, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.471, 49 CFR 173.475, 49 CFR 173.476**: Definitions, general design requirements, industrial packages, additional design requirements for Type A packages, requirements for Type B packages, authorized Type A packages, authorized Type B packages, requirements for determining A1 and A2 values for radionuclides and for the listing of radionuclides on shipping papers and labels, table of A1 and A2 values for radionuclides, radiation level

limit, requirements for U.S. NRC-approved packages, quality control requirements prior to each shipment of Class 7 (radioactive) materials, approval of special form Class 7 (radioactive) materials; and

- Carriage by Public Highway **49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842**: Driver training, shipping paper, general requirements (packages secured in a vehicle), Class 7 (radioactive) material.

For additional transportation information visit the DOT's Office of Hazardous Materials Safety web site at

<http://hazmat.dot.gov/>

Appendix X

Procedure for Waste Disposal by Decay-In-Storage, Generator Return, and Licensed Material Return

This procedure provides acceptable methods for waste disposal. Applicants may either adopt these procedures or develop alternative procedures to meet the requirements of *12 VAC 5-481-910*, *12 VAC 5-481-630*, and *12 VAC 5-481-1890*.

Procedure for Decay-In-Storage

12 VAC 5-481-1890 describes the requirements for decay-in-storage. Storage should be designed to allow for segregation of wastes with different half-lives (e.g., multiple shielded containers). Containers should have shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location.

- If possible, use separate containers for different types of waste, e.g., needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container. Because the waste will be surveyed with all shielding removed, the containers in which the waste will be disposed of must not provide any radiation shielding for the material.
- When the container is full, seal it and attach an identification tag that includes the date sealed and the longest-lived radionuclide in the container. The container may then be transferred to the decay-in-storage area.
- Prior to disposal as in-house waste, monitor and record the results of monitoring of each container as follows:
 - Use a survey instrument that is appropriate for the type and energy of the radiation being measured;
 - Check the radiation detection survey meter for proper operation and current calibration status;
 - Monitor in a low-level radiation (<0.05 millirem per hour) area away from all sources of radioactive material, if possible;
 - Remove any shielding from around the container or generator column;
 - Monitor, at contact, all surfaces of each individual container;
 - Remove or deface any radioactive material labels (unless the containers will be managed as biomedical waste after they have been released from the licensee as described in *12 VAC 5-481-1890*;
 - Discard as in-house waste only those containers that cannot be distinguished from background. Containers may include trash bags full of waste, generator columns, and biohazard (needle) boxes. Record the disposal date, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal;
 - Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred to an authorized radioactive material recipient.

Procedure for Returning Generators to the Manufacturer

Used Mo-99/Tc-99m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with VDH transportation requirements in *12 VAC 5-481-10 'Definitions'* and *12 VAC 5-481 'Virginia Radiation Protection Regulations', Part XIII 'Transportation of Radioactive Material'* and DOT regulations (incorporated by reference). Perform the following actions when returning generators:

- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container;
- Assemble the package in accordance with the manufacturer's instructions;

- Perform the dose rate and removable contamination measurements;
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions;
- Retain records of receipts and transfers in accordance with *12 VAC 5-481-100*.

Procedure for Return of Licensed Material to Authorized Recipients

Perform the following steps when returning licensed material to authorized recipients:

- In accordance with *12 VAC 5-481-570*, confirm that persons are authorized to receive radioactive material prior to transfer (e.g., obtain a copy of the transferee's VDH license, NRC or Agreement State license that authorizes the radioactive material);
- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container;
- Assemble the package in accordance with the manufacturer's instructions;
- Perform the dose rate and removable contamination measurements;
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions;
- Retain records of receipts and transfers in accordance with *12 VAC 5-481-100*.

Appendix Y

Recordkeeping Requirements

Record	Survey Requirement	Record Requirement	Retention Period
Results of surveys and calibrations	<i>12 VAC 5-481-750; 12 VAC 5-481-900</i>	<i>12 VAC 5-481-1000</i>	3 years
Results of surveys to determine dose from external sources		<i>12 VAC 5-481-1000</i>	Duration of license
Results of measurements and calculations used to determine individual intakes		<i>12 VAC 5-481-1000</i>	Duration of license
Results of air samplings, surveys and bioassays	<i>12 VAC 5-481-830</i>	<i>12 VAC 5-481-1000</i>	Duration of license
Results of measurements and calculations used to evaluate the release of radioactive effluents to the environment		<i>12 VAC 5-481-1000</i>	Duration of license
Determination of prior occupational dose		<i>12 VAC 5-481-1020</i>	Duration of license
Planned special exposure	<i>12 VAC 5-481-690</i>	<i>12 VAC 5-481-1030</i>	Duration of license
Individual monitoring results	<i>12 VAC 5-481-760</i>	<i>12 VAC 5-481-1040</i>	Duration of license
Dose to individual members of the public	<i>12 VAC 5-481-730</i>	<i>12 VAC 5-481-1050</i>	Duration of license
Waste Disposal	<i>12 VAC 5-481-910</i>	<i>12 VAC 5-481-1060</i>	Duration of license
Receipt, transfer and disposal of radioactive material	<i>12 VAC 5-481-900</i>	<i>12 VAC 5-481-100</i>	Duration of possession and 3 years thereafter
Authority and responsibilities of radiation protection program	<i>12 VAC 5-481-1700</i>	<i>12 VAC 5-481-2070</i>	5 years
Radiation protection program changes	<i>12 VAC 5-481-1700</i>	<i>12 VAC 5-481-2070</i>	5 years
Written directives	<i>12 VAC 5-481-1720</i>	<i>12 VAC 5-481-2070</i>	3 years
Calibrations of instruments used to measure activity of unsealed radioactive material	<i>12 VAC 5-481-1800</i>	<i>12 VAC 5-481-2070</i>	3 years
Radiation survey instruments calibrations	<i>12 VAC 5-481-1810</i>	<i>12 VAC 5-481-2070</i>	3 years
Dosages of unsealed radioactive material for medical use	<i>12 VAC 5-481-1820</i>	<i>12 VAC 5-481-2070</i>	3 years
Leak tests and inventory of sealed sources and brachytherapy sources	<i>12 VAC 5-481-1840</i>	<i>12 VAC 5-481-2070</i>	3 years
Surveys for ambient radiation exposure rate	<i>12 VAC 5-481-1860</i>	<i>12 VAC 5-481-2070</i>	3 years
Release of individuals containing unsealed radioactive material or implants containing radioactive material	<i>12 VAC 5-481-1870</i>	<i>12 VAC 5-481-2070</i>	3 years

Appendix Z

Reporting Requirements

EVENT	TELEPHONE NOTIFICATION	WRITTEN REPORT	HFS 157 REQUIREMENT
Reports to individuals workers	None	Annually	<i>12 VAC 5-481-2280</i>
Reports to former individual workers	None	Upon request	<i>12 VAC 5-481-2280</i>
Reports to worker terminating employment	None	Upon request	<i>12 VAC 5-481-2280</i>
Theft or lost of material	Immediate	30 days	<i>12 VAC 5-481-1090</i>
Whole body dose greater than 0.25 Sv (25 rems)	Immediate	30 days	<i>12 VAC 5-481-1100;</i> <i>12 VAC 5-481-1110</i>
Extremity dose greater than 2.5 Sv (250 rems)	Immediate	30 days	<i>12 VAC 5-481-1100);</i> <i>12 VAC 5-481-1110</i>
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	<i>12 VAC 5-481-1100;</i> <i>12 VAC 5-481-1110</i>
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	<i>12 VAC 5-481-1100;</i> <i>12 VAC 5-481-1110</i>
Doses in excess of specified criteria	None	30 days	<i>12 VAC 5-481-1110</i>
Levels of radiation or concentrations of radioactive material in excess of specified criteria	None	30 days	<i>12 VAC 5-481-1110</i>
Planned special exposure	None	30 days	<i>12 VAC 5-481-1120</i>
Report to individuals of exceeding dose limits	None	30 days	<i>12 VAC 5-481-1110</i>
Report of individual monitoring	None	Annually	<i>12 VAC 5-481-1130</i>
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	Immediate	30 days	<i>12 VAC 5-481-1100</i>
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	<i>12 VAC 5-481-1100</i>
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	<i>12 VAC 5-481-1100</i>
Licensee permits individual to work as AU, ANP, or AMP	None	30 days	<i>12 VAC 5-481-1690</i>