VIRGINIA DEPARTMENT OF HEALTH

DIVISION OF RADIOLOGICAL HEALTH

NRC AGREEMENT STATE APPLICATION

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

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

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

This VAREG, 'Guidance for 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 **12VAC5-491** 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
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 **12VAC5-481 '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;
- Theraputic 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 **12VAC5-481-2060**, 'Other medical uses of byproduct material or radiation from byproduct material.' Therefore, VDH Radioactive Material Program 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 **12VAC5-481 'Virginia Radiation Protection Regulations'** applicable to the item;
- **Criteria** – outlines the criteria used to judge the adequacy of the applicant's response;
- **Discussion** – provides additional information on the topic sufficient to meet the needs of most readers; 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.

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

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

This VAREG provides the latest guidance and is modeled on the Nuclear Regulatory Commission's (NRC) NUREG 1556, Volume 9. The VAREG shows the requirements in terms of the **12VAC5-481 'Virginia Radiation Protection Regulations'** and provides a user-friendly format to assist with the preparation of a 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 **12VAC5-481 '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 **12VAC5-481-430 G**, 'General license for use of byproduct 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/Epidemiology/RadiologicalHealth/ 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 **12VAC5-481 '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 **12VAC5-481-430 G** at any one time, at any one location of storage or use. The use of materials listed in **12VAC5-481-430 G** within the inventory limits of that section is subject only to the requirements of that section and not to the requirements of **12VAC5-481 '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 **12VAC5-481-430 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 **12VAC5-481 '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 **12VAC5-481-450 A** 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 **12VAC5- 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 (**12VAC5-481-1880, 12VAC5- 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 **12VAC5-481 'Virginia Radiation Protection Regulations', Part III 'Licensing of Radioactive Materials'**. The criteria for the various types of broad scope licenses are found in **12VAC5-480-470.** 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

12VAC5-481-630, Radiation protection programs, states that *"each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities"* and *"the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are...ALARA."* This section also requires that licensees review the content of the radiation protection program and its implementation annually.

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 **12VAC5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation'**, is contained in:

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

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

WRITTEN DIRECTIVE (WD) PROCEDURES

12VAC5-481-1730 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

12VAC5-481-10 defines "*medical use*" to include the administration of radioactive material to human research subjects. Furthermore, **12VAC5-481-1670**, '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 **12VAC5-481-1670**, 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 **12VAC5-481-1670**, 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 **12VAC5-481-1670**, 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 [*10 CFR 30.12*])	NRC
Non-federal entity in non-Agreement State, U.S. territory, or possession	NRC
Non-federal entity in Virginia at non-federally controlled site	VDH
Non-federal entity in Virginia at federally-controlled site not subject to exclusive federal jurisdiction	VDH
Non-federal entity in Virginia at federally-controlled site subject to exclusive federal jurisdiction	NRC

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

MANAGEMENT RESPONSIBILITY

VDH endorses the philosophy that effective radiation protection program management is vital to safe operations that comply with VDH regulatory requirements (see **12VAC5-481-1700).**

"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 **12VAC5-481-450** and **12VAC5-481-1700**, 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 **12VAC5-481 'Virginia Radiation Protection Regulations'**.

The following parts of **12VAC5-481 '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/Epidemiology/RadiologicalHealth/.

HOW TO FILE

Applicants for a materials license should do the following:

- Be sure to use the current guidance from VDH in preparing an application.
- Complete VDH Form 'Application for Radioactive Material License for 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 11inch 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.

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

WHERE TO FILE

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

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

LICENSE FEES

The appropriate fee must accompany each application or license amendment request. Refer to **12VAC5-491** to determine the amount of the fee. VDH will not issue the new license prior to fee receipt. Once technical review has begun, no fees will be refunded. Application fees will be charged regardless of VDH's disposition of an application or the withdrawal of an application.

Licensees are also subject to annual fees; refer to **12VAC5-491**.

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 charges 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.

Response from Applicant:

Item 1. Type Of Application (Check one box)
☐ New License ☐ Renewal License Number _____

Item 2: Applicant's Name and Mailing Address

Rule: 12VAC5-481-500; 12VAC5-481-1690

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

Response from Applicant:

Item 2. Name and Mailing Address of Applicant
Applicant's Telephone Number (Include Area Code)

Note: VDH must be notified before control of the license is transferred or whenever bankruptcy proceedings are initiated. See below for more details. NRC's IN 97-30, 'Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises,' dated June 3, 1997, discusses the potential for the security and control of licensed material to be compromised during periods of organizational instability.

Timely Notification of Transfer of Control

Rule: 12VAC5-481-500; 12VAC5-481-1690

Criteria: Licensees must provide full information and obtain VDH's written consent before transferring control of the license, or, as some licensees refer to the process, 'transferring the license'.

Discussion: Control may be transferred as a result of mergers, buyouts, or majority stock transfers. Although it is not VDH's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain VDH written consent before transferring control of the license. This is to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid VDH 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 final disposal of the material; and
- Public health and safety are not compromised by the use of such materials.

As provided in **12VAC5-481-1690**, 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 **12VAC5-481-1690**, 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: 12VAC5-481-500

Criteria: 12VAC5-481-500 states: "*Each licensee shall notify the agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against: 1. The licensee 2. An entity (as that term is defined in 11 USC §101 (15)) controlling the licensee or listing the license or licensee as property of the estate; or 3. An affiliate (as that term is defined in 11 USC §101 (2)) of the licensee*" and "*...shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of filing of the petition*".

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

Licensees must notify VDH 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 3: Person to be Contacted about this Application

Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the proposed RSO, unless the applicant has named a different person as the contact. VDH will contact this individual if there are questions about the application.

Notify VDH of changes of contact name or telephone number so that VDH can contact the applicant or licensee in the future with questions, concerns, or information. This notice is for 'information only' and does not require a license amendment or a fee.

The individual named in **Item 3** of the application form may or may not be the same individual who signs the application as the 'certifying officer' on behalf of the licensee with the authority to make commitments to VDH (see **Item 12** on VDH Form 'Application for Radioactive Material License for Medical Use' (**Appendix A**)). Any commitments the applicant makes should be signed by the individual named in **Item 12** since only that individual is considered by VDH to have the authority to make commitments on behalf of the applicant. VDH will not accept license renewals signed by the individual identified in **Item 3** if this person differs from the one named in **Item 12**. The individual named in **Item 12** may delegate the authority to submit routine license amendments to an assigned individual such as an RSO or authorized user. VDH will accept a written delegation and incorporate this as a license commitment (tie-down), thus accepting routine license amendments from a designated individual. **Appendix F** contains sample text which may be used to delegate correspondence authority to a designated individual.

VDH recognizes that licensees may use a consultant to help prepare the license application and provide support to the radiation protection program. However, VDH reminds licensees that regardless of the role of the consultant in radiation protection program management, the licensee remains responsible for all aspects of the licensed program, including the services performed by the consultant.

Response from Applicant:

Item 3. Person to contact regarding this application:
Contact's Telephone Number (Include Area Code):

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

Rule: 12VAC5-481-450 A; 12VAC5-481-500; 12VAC5-481-1880

Pursuant to **12VAC5-481-500** 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 **12VAC5-481-1880**, 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).

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? ☐ 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.	

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

Rule: 12VAC5-481-450 A; 12VAC5-481-1700; 12VAC5-481-1750; 12VAC5-481-1760; 12VAC5-481-1770; 12VAC5-481-1780; 12VAC5-481-1790; 12VAC5-481-1910; 12VAC5-481-1940; 12 VAC-5-481-1980; 12VAC5-481-1990; 12VAC5-481-2000; 12VAC5-481-2001; 12VAC5-481-2010; 12VAC5-481-2030; 12VAC5-481-2040

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: 12VAC5-481-1700 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). **12VAC5-481-450 A** 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. **12VAC5-481-1750, 12VAC5-481-1760, 12VAC5-481-1770, 12VAC5-481-1780, 12VAC5-481-1910, 12VAC5-481-1940, 12VAC5-481-1980, 12VAC5-481-1990, 12VAC5-481-2000, 12VAC5-481-2001; 12VAC5-481-2010, 12VAC5-481-2030, and 12VAC5-481-2040** give specific criteria for acceptable training and experience for AUs for medical use, ANPs, the RSO, and AMPs.

A résumé or 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**).

Licensees 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.

Licensees that are authorized for two or more different types of uses of radioactive material under **12VAC5-481-1950, 12VAC5-481-2010, 12VAC5-481-2040** or two or more types of units under **12VAC5-481-2040** 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.

Licensees 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: 12VAC5-481-450 A; 12VAC5-481-630; 12VAC5-481-1680; 12VAC5-481-1690; 12VAC5-481-1700; 12VAC5-481-1750; 12VAC5-481-1760; 12VAC5-481-1780; 12VAC5-481-1790; 12VAC5-481-2070

Criteria: RSOs must have adequate training and experience. The training and experience requirements for the RSO are described in **12VAC5-481-1750** and allow for the following training pathways:

- Certification as provided in **12VAC5-481-1750** by one of the professional boards recognized by VDH and written attestation signed by a preceptor RSO as provided in **12VAC5-481-1750.**
- Classroom and laboratory training (200 hours) and 1 year of work experience as described in **12VAC5-481-1750** and written attestation signed by a preceptor RSO as provided in **12VAC5-481-1750**.

- For medical physicists, certification by a specialty board whose certification process has been recognized by VDH under **12VAC5-481-1760**, 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 **12VAC5-481-1750.**
- 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 **12VAC5-481-1700**, 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 **12VAC5-481-1700** 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 **12VAC5-481-1700**.

Applicants are reminded of recentness of training requirements described in **12VAC5-481-1790**. Specifically, RSO applicants must have successfully completed the applicable training and experience criteria described in **12VAC5-481 '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 another 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 **12VAC5-481-1750** 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 **12VAC5-481-1750** 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 **12VAC5-481-1750** 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 **12VAC5-481-1790**.

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 **(12VAC5-481-1690)** and must request an amendment to change an RSO **(12VAC5-481-1680)**.
- The licensee must notify VDH within 30 days if an RSO has a name change **(12VAC5-481-1690)**.
- 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 **12VAC5-481-1700**, 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 **12VAC5-481-1750** 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.

- It is important to notify the agency and obtain a license amendment prior to making changes in the designation of the RSO responsible for the radiation safety program. If the RSO leaves the organization before an amendment is approved by VDH, a potential designee, who meets the RSO qualification requirements, is responsible for ensuring that the licensee's radiation safety program is implemented in accordance with the license and VDH rule.

Item 5.2: Authorized Users (AUs)

Rule: 12VAC5-481-450 A; 12VAC5-481-1670; 12VAC5-481-1690; 12VAC5-481-1710; 12VAC5-481-1780; 12VAC5-481-1790; 12VAC5-481-1910; 12VAC5-481-1940; 12VAC5-481-1980; 12VAC5-481-1990; 12VAC5-481-2000; 12VAC5-481-2001; 12VAC5-481-2010; 12VAC5-481-2020; 12VAC5-481-2030; 12VAC5-481-2040; 12VAC5-481-2270

Criteria: Training and experience requirements for physician AUs are described in **12VAC5-481-1910; 12VAC5-481-1940; 12VAC5-481-1980; 12VAC5-481-1990; 12VAC5-481-2000; 12VAC5-481-2001; 12VAC5-481-2010; 12VAC5-481-2030; 12VAC5-481-2040;** and **12VAC5-481-2270**

Discussion: An AU is defined in **12VAC5-481-10**. 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.

12VAC5-481-1780 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 **12VAC5-481 '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 **12VAC5-481-1710** and in compliance with applicable FDA, other Federal, and State requirements (**12VAC5-481-1670**). 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, **12VAC5-481 '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 **12VAC5-481-1790**. Specifically, physician AU applicants must have successfully completed the applicable training and experience criteria described in **12VAC5-481 '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 another 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 **12VAC5-481-1910; 12VAC5-481-1940; 12VAC5-481-1960; 12VAC5-481-1980; 12VAC5-481-1990; 12VAC5-481-2000; 12VAC5-481-2001; 12VAC5-481-2010; 12VAC5-481-2030; 12VAC5-481-2040**, 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 **12VAC5-481-1910; 12VAC5-481-1940; 12VAC5-481-1960; 12VAC5-481-1980; 12VAC5-481-1990; 12VAC5-481-2000; 12VAC5-481-2001; 12VAC5-481-2010; 12VAC5-481-2030; 12VAC5-481-2040**, 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 **12VAC5-481-1910; 12VAC5-481-1940; 12VAC5-481-1960; 12VAC5-481-1980; 12VAC5-481-1990; 12VAC5-481-2000; 12VAC5-481-2001; 12VAC5-481-2010; 12VAC5-481-2040** 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 **12VAC5-481-1790**.

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 **12VAC5-481-1690**.
- 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 **12VAC5-481 '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: 12VAC5-481-450 A; 12VAC5-481-1670; 12VAC5-481-1690; 12VAC5-481-1710; 12VAC5-481-1770; 12VAC5-481-1780; 12VAC5-481-1790

Criteria: Training and experience requirements for ANPs are described in **12VAC5-481-1770.**

Discussion: An ANP is defined in **12VAC5-481-10**. 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 **12VAC5-481-1710,** and in compliance with applicable U.S. Food and Drug Administration (FDA), other Federal, and State requirements (**12VAC5-481-1670**). 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 **12VAC5-481-1790**. Specifically, nuclear pharmacist applicants must have successfully completed the applicable training and experience criteria described in **12VAC5-481 '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 another 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 **12VAC5-481-1770** 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 **12VAC5-481-1770** 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 **12VAC5-481-1770** 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 **12VAC5-481-1790**.

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 **12VAC5-481-1690**.
- 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 **12VAC5-481 '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 **12VAC5-481 '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: 12VAC5-481-450 A; 12VAC5-481-1690; 12VAC5-481-1760; 12VAC5-481-1780; 12VAC5-481-1790

Criteria: Training and experience requirements for AMPs are described in **12VAC5-481-1760.**

Discussion: An AMP is defined in **12VAC5-481-10**. 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 **12VAC5-481-1790.** Specifically, medical physicist applicants must have successfully completed the applicable training and experience criteria described in **12VAC5-481 '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 another 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 **12VAC5-481-1760** 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 **12VAC5-481-1760** 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 **12VAC5-481-1760** 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 **12VAC5-481-1790.**

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 **12VAC5-481-1690**.
- 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 **12VAC5-481 '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 **12VAC5-481 '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: 12VAC5-481-1710; 12VAC5-481-1870; 12VAC5-481-1960; 12VAC5-481-1970; 12VAC5-481-2010; 12VAC5-481-2040; 12VAC5-481-2070; 12VAC5-481-2270

Criteria: Individuals working with or in the vicinity of licensed material must have adequate safety instruction as required by **12VAC5-481 '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 **12VAC5-481-2270**. Additional requirements for training in radiation safety for individuals involved with therapeutic treatment of patients are described in **12VAC5-481-1960, 12VAC5-481-2010,** and **12VAC5-481-2040**. Records of safety instruction provided must be maintained in accordance with **12VAC5-481-2070**. **12VAC5-481-1710** 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 **12VAC5-481-2270**. 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 **12VAC5-481-2270** and in accordance with **12VAC5-481-1960, 12VAC5-481-2010,** and **12VAC5-481-2040**, 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 **12VAC5-481-1870**. 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 **12VAC5-481-1710**, 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 **12VAC5-481-1710**, 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. **12VAC5-481-1710** states that a licensee that permits supervised activities is responsible for the acts and omissions of the supervised individuals.

Procedures describing the training programs are provided in **Appendix H.**

Response from Applicant:

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 Use 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)

Item 7: Radioactive Material

Rule: 12VAC5-481-440; 12VAC5-481-450; 12VAC5-481-500; 12VAC5-481-1680; 12VAC5-481-1830; 12VAC5-481-1900; 12VAC5-481-1920; 12VAC5-481-1950; 12VAC5-481-2010; 12VAC5-481-2020; 12VAC5-481-2040; 12VAC5-481-2060

Criteria: 12VAC5-481 '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:

12VAC5-481-1900	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required
12VAC5-481-1920	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required
12VAC5-481-1950	Use of unsealed by product material for which a written directive is required
12VAC5-481-2010	Manual brachytherapy

12VAC5-481-2010	Manual brachytherapy
12VAC5-481-2020	Use of sealed sources for diagnosis
12VAC5-481-2040	Teletherapy Units
12VAC5-481-2040	Photon Emitting Remote Afterloader Units
12VAC5-481-2040	Stereotactic Radiosurgery Units
12VAC5-481-2060	Other medical uses of byproduct material or radiation from byproduct materials

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: 12VAC5-481-430 G; 12VAC5-481-440; 12VAC5-481-450; 12VAC5-481-470; 12VAC5-481-1680; 12VAC5-481-1830; 12VAC5-481-1900; 12VAC5-481-1920; 12VAC5-481-1950; 12VAC5-481-2010; 12VAC5-481-2020; 12VAC5-481-2040; 12VAC5-481-2060

Criteria: 12VAC5-481 'Virginia Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts', divides radioactive material for medical use into seven

types of use **12VAC5-481-1900; 12VAC5-481-1920; 12VAC5-481-1950; 12VAC5-481-2010; 12VAC5-481-2020; 12VAC5-481-2040** and **12VAC5-481-2060.**

Discussion: For *in vitro* use exceeding general license limits under **12VAC5-481-430 G,** calibration sources exceeding the exemptions listed is **12VAC5-481-1830**, uptake, dilution and excretion studies under **12VAC5-481-1900,** and imaging and localization studies under **12VAC5-481-1920**, the applicant should select the type of use.

The use of unsealed radioactive material in therapy **(12VAC5-481-1950)** 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 **12VAC5-481-1950**, 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 **12VAC5-481-1950**, 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 **12VAC5-481-2010** 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 **12VAC5-481-2010**, 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 **12VAC5-481-2010** 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 **12VAC5-481-2020** 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 **12VAC5-481-2020** 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 **12VAC5-481-2040** 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 **12VAC5-481-440**, 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.

12VAC5-481-2060 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 **12VAC5-481-2060** when the desired type of use isn't covered elsewhere in **12VAC5-481 '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 **12VAC5-481-2060** 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 **12VAC5-481-1680:**

- 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 **12VAC5-481-470** from selected requirements in **12VAC5-481-1680** 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 **12VAC5-481-1830**, '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
☐ Use of Radioactive Material for Certain In-Vitro Clinical or laboratory testing if maximum activity exceeds 200 μCi **(12VAC5-481-430 G)**	Any	As needed	N/A	N/A
☐ Use of Calibration, Transmission, and Reference Sources not included in **12VAC5-481-1830** (e.g., bone densitometry sources, fluorine-18 calibration sources)	Attach a detailed description of the radioactive material and intended use.		N/A	N/A
☐ Unsealed Radioactive Material for Uptake, Dilution and Excretion Studies for Which a Written Directive is not Required **(12VAC5-481-1900)**	Any	As needed	N/A	N/A
☐ Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is not Required **(12VAC5-481-1920)**	Any	As needed	N/A	N/A
☐ Unsealed Radioactive Material for Which a Written Directive is Required **(12VAC5-481-1950)**	Any		N/A	N/A
☐ Unsealed Radioactive Material for Which a Written Directive is Required Specific radiopharmaceuticals **(12VAC5-481-1950)**	For this type of use attach a detailed description of radiopharmaceutical, form, route of administration and therapeutic use.		N/A	N/A
☐ Sources for Manual Brachytherapy **(12VAC5-481-2010)**	Sealed Source			
☐ Sources for Manual Brachytherapy – Ophthalmic Use Only **(12VAC5-481-2010)**	Sealed Source			
☐ Sealed Sources for Diagnosis **(12VAC5-481-2020)**	Sealed Source			
☐ Sealed Source(s) in a Device for Therapy – Teletherapy Unit **(12VAC5-481-2040)**	Sealed Source			
☐ Sealed Source(s) in a Device for Therapy – Remote Afterloader Unit **(12VAC5-481-2040)**	Sealed Source			
☐ Sealed Source(s) in a Device for Therapy – Gamma Stereotactic Radiosurgery Unit **(12VAC5-481-2040)**	Sealed Source			
☐ Other Medical Use of Radioactive Material or Radiation from Radioactive Material (e.g. Emerging Technology) **(12VAC5-481-2060)**	For this type of use attach a detailed description of the radioactive material and intended use			
☐ Non-medical use of radioactive material	Attach a detailed description of the radioactive material and intended use.			

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: 12VAC5-481-450 C; 12VAC5-481-500; 12VAC5-481-510; 12VAC5-481-1161; 12VAC5-481-1680

Criteria: All licensees are required to maintain records important to decommissioning. Licensees authorized to possess licensed material in excess of the limits specified in **12VAC5-481-450 C** must provide evidence of financial assurance for decommissioning.

Even if no financial assurance is required, licensees are required, under **12VAC5-481-450 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 **12VAC5-481-500**, 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 **12VAC5-481-450 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 **12VAC5-481-450 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 **12VAC5-481-450 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

Licensees using sealed sources authorized by **12VAC5-481 '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: 12VAC5-481-440; 12VAC5-481-450 A; 12VAC5-481-1830

Criteria: In accordance with **12VAC5-481-440**, 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 **12VAC5-481-1830**). Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by NRC or another Agreement State.

Discussion: The NRC or another 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 Sealed Source and Device Registration Certificate (SSDR). 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 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 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 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: 12VAC5-481-100; 12VAC5-481-450; 12VAC5-481-500; 12VAC5-481-510; 12VAC5-481-570; 12VAC5-481-571; 12VAC5-481-1161; 12VAC5-481-1690

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 **12VAC5-481-510**;
- Conduct decommissioning, as required by **12VAC5-481-1161**; 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 **12VAC5-481-500**, 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 the VDH Form, '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: 12VAC5-481-450 A

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

Discussion: In **12VAC5-481-450 A**, 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: 12VAC5-481-10; 12VAC5-481-440; 12VAC5-481-450; 12VAC5-481-500; 12VAC5-481-630; 12VAC5-481-640; 12VAC5-481-720; 13 VAC 5-481-730; 12VAC5-481-780; 12VAC5-481-790; 12VAC5-481-850; 12VAC5-481-860; 12VAC5-481-990; 12VAC5-481-1680; 12VAC5-481-1690; 12VAC5-481-1870; 12VAC5-481-1900; 12VAC5-481-1920; 12VAC5-481-1950; 12VAC5-481-2010; 12VAC5-481-2020; 12VAC5-481-2040; 12VAC5-481-2060

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 **12VAC5-481-440, 12VAC5-481-450,** and **12VAC5-481-500.** 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 **12VAC5-481-1900** and **12VAC5-481-1920**, 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 **12VAC5-481-1950** and **12VAC5-481-2010**, 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 **12VAC5-481-1870**. The discussion should include a description of shielding, if applicable. For types of use permitted by **12VAC5-481-2020,** the applicant should provide the room numbers of use.

For types of use permitted by **12VAC5-481-2040,** 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 **12VAC5-481-2060,** applicants should review the above to determine the type of information appropriate to evaluate the adequacy of the facilities.

Licensees are required by **12VAC5-481-1680** 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 **12VAC5-481-1900** and **12VAC5-481-1920**.

Licensees are required by **12VAC5-481-1690** to notify VDH within 30 days following changes in areas of use for **12VAC5-481-1900** and **12VAC5-481-1920** 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.

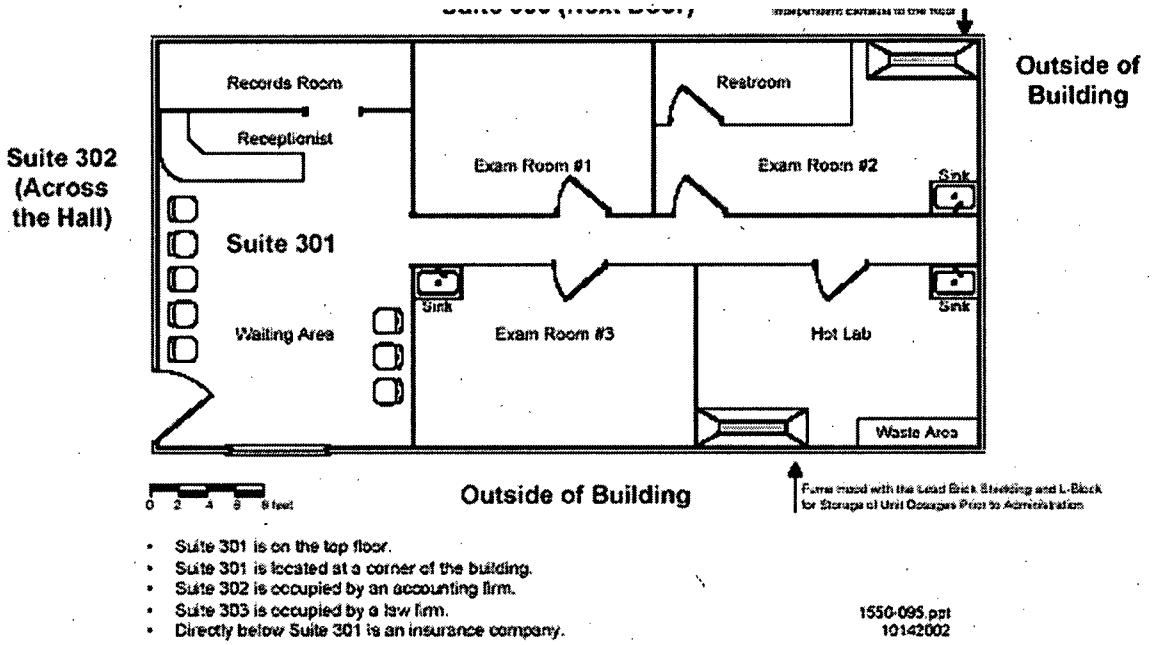

Figure 1: Facility Diagram for Nuclear Medicine Suite

The applicant should demonstrate that the limits specified in **12VAC5-481-720** 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 **12VAC5-481-720** 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 **12VAC5-481-720**. 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 **12VAC5-481-720**, 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 **12VAC5-481-10**; 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.

Item 8.2: Radiation Monitoring Instrumentation

Rule: 12VAC5-481-450 A; 12VAC5-481-630; 12VAC5-481-750; 12VAC5-481-1000; 12VAC5-481-1710; 12VAC5-481-1810; 12VAC5-481-2070

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 **12VAC5-481-630** must include provisions for survey instrument calibration (**12VAC5-481-750**). 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 ratemeter, 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: 12VAC5-481-450; 12VAC5-481-1710; 12VAC5-481-1730; 12VAC5-481-1800; 12VAC5-481-1820; 12VAC5-481-2070

Criteria: In **12VAC5-481-1800** and **12VAC5-481-1820**, 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 **12VAC5-481-1820**, 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 **12VAC5-481-1820**, 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 **12VAC5-481-1800**, if the licensee performs direct measurements of dosages in accordance with **12VAC5-481-1820** (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:

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

Rule: 12VAC5-481-450 A; 12VAC5-481-1710; 12VAC5-481-1730; 12VAC5-481-2010; 12VAC5-481-2040; 12VAC5-481-2070

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 **12VAC5-481 '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 **12VAC5-481-2040**. 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 **12VAC5-481-2010** 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 (**12VAC5-481-2040**). 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 **12VAC5-481-2040.**

12VAC5-481-2010 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 **12VAC5-481-2040**.

AND

☐ We have developed and will implement a written calibration procedure for a therapy sealed source that meets the requirements in **12VAC5-481-2010** and **12VAC5-481-2040** (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: 12VAC5-481-450 A; 12VAC5-481-500; 12VAC5-481-630; 12VAC5-481-840; 12VAC5-481-1870; 12VAC5-481-1890; 12VAC5-481-1970; 12VAC5-481-2010; 12VAC5-481-2040

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 **12VAC5-481-1870** 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 **12VAC5-481-2040**. 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 **12VAC5-481-2040**, 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. **12VAC5-481-2040**, 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 **12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-840,** and **12VAC5-481-2040** 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: 12VAC5-481-450; 12VAC5-481-490; 12VAC5-481-500; 12VAC5-481-630; 12VAC5-481-990; 12VAC5-481-1690; 12VAC5-481-1700; 12VAC5-481-2070

Criteria: 12VAC5-481-630 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 **12VAC5-481 '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. **12VAC5-481-490** 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, **12VAC5-481-630** and **12VAC5-481-1700** describes the licensee management's authorities and responsibilities for the radiation protection program. **12VAC5-481-1700** 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: 12VAC5-481-630; 12VAC5-481-990

Criteria: Under **12VAC5-481-630**, 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 (**12VAC5-481-630**);
- 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 **12VAC5-481-990**, 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: 12VAC5-481-10; 12VAC5-481-630; 12VAC5-481-640; 12VAC5-481-650; 12VAC5-481-670; 12VAC5-481-700; 12VAC5-481-710; 12VAC5-481-750; 12VAC5-481-760; 12VAC5-481-770; 12VAC5-481-1040; 12VAC5-481-1710; 12VAC5-481-2070; 12VAC5-481-2280

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 **(12VAC5-481-760).**

Table 4: Occupational Dose Limits for Adults

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

Table 5: 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 **12VAC5-481-630**, 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 **12VAC5-481-760**. 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 **12VAC5-481 '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 **12VAC5-481 '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 **12VAC5-481-750**.

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 **12VAC5-481-750**, 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 **12VAC5-481-650, 12VAC5-481-670,** and **12VAC5-481-760**. 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 (H_s)*" in **12VAC5-481-10** 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"*).

12VAC5-481-650 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 **12VAC5-481-760** and that meet the requirements in **12VAC5-481 '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: 12VAC5-481-10; 12VAC5-481-720; 12VAC5-481-730; 12VAC5-481-840; 12VAC5-481-1050; 12VAC5-481-1110; 12VAC5-481-1870

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 **12VAC5-481-10** does not include doses received due to exposure to patients released in accordance with **12VAC5-481-1870**. Dose to members of the public in waiting rooms was addressed in the NRC Information Notice (IN) 94-09. The provisions of **12VAC5-481-720** should not be applied to radiation received by a member of the general public from patients released under **12VAC5-481-1870**. If a patient is released pursuant to **12VAC5-481-1870**, 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 **12VAC5-481-1870.**

12VAC5-481-720 allows licensees to permit visitors to a patient who cannot be released under **12VAC5-481-1870** to receive a dose greater than 1 mSv (0.1 rem) provided the dose does not exceed 5 mSv (0.5 rem) and the AU 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 **12VAC5-481-1110** 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: 12VAC5-481-450 A; 12VAC5-481-1840

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 another 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:

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

Rule: 12VAC5-481-500; 12VAC5-481-630; 12VAC5-481-750; 12VAC5-481-780; 12VAC5-481-790; 12VAC5-481-840; 12VAC5-481-900; 12VAC5-481-910; 12VAC5-481-1090; 12VAC5-481-1100; 12VAC5-481-1110; 12VAC5-481-1150; 12VAC5-481-1710; 12VAC5-481-1730; 12VAC5-481-1860; 12VAC5-481-1870; 12VAC5-481-1890; 12VAC5-481-1960; 12VAC5-481-1970; 12VAC5-481-2010; 12VAC5-481-2040; 12VAC5-481-2080; 12VAC5-481-2260; 12VAC5-481-3700

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 **12VAC5-481-1870**;
- 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 **12VAC5-481-630** 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. **12VAC5-481-780, 12VAC5-481-790,** and **12VAC5-481-840** 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 **12VAC5-481-3700** 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 **(12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1150,** and **12VAC5-481-2080)** 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: 12VAC5-481-100; 12VAC5-481-500; 12VAC5-481-570; 12VAC5-481-571; 12VAC5-481-840; 12VAC5-481-900; 12VAC5-481-1090; 12VAC5-481-1710; 12VAC5-481-1840; 12VAC5-481-2070

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.

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

Response from Applicant:

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

Rule: 12VAC5-481-100; 12VAC5-481-500; 12VAC5-481-570; 12VAC5-481-571; 12VAC5-481-840; 12VAC5-481-900; 12VAC5-481-3091

Criteria: 12VAC5-481-900 contains the requirements for receiving packages containing licensed material. Additionally, the security of licensed material, required by **12VAC5-481-840,** must be considered for all receiving areas. **12VAC5-481-100** and **12VAC5-481-571** 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: 12VAC5-481-750; 12VAC5-481-900; 12VAC5-481-1000; 12VAC5-481-3091

Criteria: Licensees must ensure that packages are opened safely and that the requirements of **12VAC5-481-900** are met. Licensees must retain records of package surveys in accordance with **12VAC5-481-1000**.

Discussion: Licensees must establish, maintain, and retain written procedures for safely opening packages to ensure that the monitoring requirements of **12VAC5-481-900** 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 **12VAC5-481-900** 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: 12VAC5-481-740; 12VAC5-481-750; 12VAC5-481-1010; 12VAC5-481-1150; 12VAC5-481-1840; 12VAC5-481-2070; 12VAC5-481-2080

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 **12VAC5-481-1840**. **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. **12VAC5-481-1840** requires licensees to perform leak tests at six-month intervals or at other intervals approved by VDH, NRC, or another Agreement State and as 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 μCi) 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 μCi) or less of beta-emitting or gamma-emitting material, or 0.37 MBq (10 μCi) 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 **(12VAC5-481-740)**. 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 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.

List the name and license number of organization authorized to perform or analyze leak test (Specify whether VDH, NRC, or another 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: 12VAC5-481-10; 12VAC5-481-630; 12VAC5-481-640; 12VAC5-481-720; 12VAC5-481-730; 12VAC5-481-750; 12VAC5-481-840; 12VAC5-481-1000; 12VAC5-481-1050; 12VAC5-481-1710; 12VAC5-481-1860; 12VAC5-481-2070

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 **12VAC5-481-640**;
- 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 **12VAC5-481-630**.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with **12VAC5-481-630** 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. 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: 12VAC5-481-1710; 12VAC5-481-1720; 12VAC5-481-1730; 12VAC5-481-2070

Criteria: 12VAC5-481-1720 sets forth the requirements for Written Directives (WDs). **12VAC5-481-1730** 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:

Item 9.11 Procedures For Administration of Radioactive Material Requiring A Written Directive (Check one box)
☐ 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'.
OR
☐ Not Applicable.

Item 9.12: Safe Use of Unsealed Licensed Material

Rule: 12VAC5-481-450 A; 12VAC5-481-500; 12VAC5-481-630; 12VAC5-481-640; 12VAC5-481-720; 12VAC5-481-730; 12VAC5-481-840; 12VAC5-481-1000; 12VAC5-481-1710; 12VAC5-481-1850; 12VAC5-481-1860; 12VAC5-481-1960; 12VAC5-481-1970

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 **12VAC5-481-630** 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)	
☐	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: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources

Rule: 12VAC5-481-440; 12VAC5-481-500; 12VAC5-481-630; 12VAC5-481-2040; 12VAC5-481-2070

Criteria: In accordance with **12VAC5-481-2040**, 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, **12VAC5-481-2040** 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 another 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 **12VAC5-481-2040** before responding to this item. **12VAC5-481-2040** allows for an AMP to perform certain service activities with regard to LDR remote afterloader units.

Response from Applicant:

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.

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: 12VAC5-481-100; 12VAC5-481-450 A; 12VAC5-481-500; 12VAC5-481-570; 12VAC5-481-630; 12VAC5-481-670; 12VAC5-481-1000; 12VAC5-481-1100; 12VAC5-481-1110; 12VAC5-481-1710; 12VAC5-481-2260; 12VAC5-481-2070

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 **12VAC5-481-630** 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:

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 Medical Use of Radioactive Material'.
OR
☐ Not Applicable. (Unsealed radioactive material not used)

Note: 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. The Virginia 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 Virginia Department of Emergency Management's 24 hour emergency telephone number: 1-800-468-8892. Identify the emergency as radiological.

Item 9.15: Emergency Response for Sealed Sources or Devices Containing Sealed Sources

Rule: 12VAC5-481-100; 12VAC5-481-450; 12VAC5-481-500; 12VAC5-481-630; 12VAC5-481-1090; 12VAC5-481-1100; 12VAC5-481-1110; 12VAC5-481-1710; 12VAC5-481-2010; 12VAC5-481-2040; 12VAC5-481-2070; 12VAC5-481-2080; 12VAC5-481-2260

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 **12VAC5-481-2040** 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 **12VAC5-481-630** 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 non-radioactive (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: 12VAC5-481-1710; 12VAC5-481-1870; 12VAC5-481-2070

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 **12VAC5-481-1870**.

Discussion: 12VAC5-481-1870 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, **12VAC5-481-1870** and **12VAC5-481-2070** 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 **12VAC5-481-1870** and **12VAC5-481-2070,** 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 **12VAC5-481-1870 (Section U.2 of Appendix U)**.

Guidance on recordkeeping requirements in **12VAC5-481-1870** and **12VAC5-481-2070** 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 **12VAC5-481-1870**.

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 **12VAC5-481-1900** & **12VAC5-481-1920**)

Item 9.17: Mobile Medical Service

Rule: 12VAC5-481-10; 12VAC5-481-100; 12VAC5-481-570; 12VAC5-481-571; 12VAC5-481-590; 12VAC5-481-630; 12VAC5-481-1680; 12VAC5-481-1870; 12VAC5-481-1880; 12VAC5-481-2040; 12VAC5-481-2070; 12VAC5-481-2980; 12VAC5-481-3000; 12VAC5-481-3010; 12VAC5-481-3020; 12VAC5-481-3030; 49 CFR Parts 171-178

Criteria: In addition to the requirements in **12VAC5-481-1880,** 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 **12VAC5-481 '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 **12VAC5-481-1870** 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 other Agreement State licensees that request reciprocity for activities conducted in the Commonwealth of Virginia are subject to the general license provisions described in **12VAC5-481-590**. This general license authorizes persons holding a specific license from the NRC or another Agreement State to conduct the same activity in the Commonwealth of Virginia if the specific license issued by the NRC or another Agreement State does not limit the authorized activity to specific locations or installations.

Item 9.18: Transportation

Rule: 12VAC5-481-100; 12VAC5-481-570; 12VAC5-481-571; 12VAC5-481-630; 12VAC5-481-2970; 12VAC5-481-2980; 12VAC5-481-3000; 12VAC5-481-3010; 12VAC5-481-3020; 12VAC5-481-3030; 12VAC5-481-3070; 12VAC5-481-3080; 12VAC5-481-3130; 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 VDH 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 excepted 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 **12VAC5-481-3000**, '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. **12VAC5-481-**

2980 sets forth the requirements for transportation of radioactive material. **12VAC5-481-2970** exempts any physician licensed by a state to dispense drugs in the practice of medicine, who is also licensed under **12VAC5-481 'Virginia Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts',** or the equivalent NRC or another Agreement State regulations from the requirements in **12VAC5-481-2980**. 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. **12VAC5-481-3000, 12VAC5-481-3010, 12VAC5-481-3020** and **12VAC5-481-3030** 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 **12VAC5-481-3000** or **12VAC5-481-3030**, 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 **12VAC5-481-2980** 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 9.18 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 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: 12VAC5-481-100; 12VAC5-481-571; 12VAC5-481-840; 12VAC5-481-1840; 12VAC5-481-2010; 12VAC5-481-2070

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 **12VAC5-481-1840**, 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 **12VAC5-481-1840**. However, the licensee must maintain records of GSR source receipt, transfer, and disposal, under **12VAC5-481-100** and **12VAC5-481-571**, to indicate the current inventory of sources at the licensee's facility. The licensee shall retain each inventory record in accordance with **12VAC5-481-2070**. In addition, **12VAC5-481-2010** and **12VAC5-481-2070** 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 9.19 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: 12VAC5-481-100; 12VAC5-481-480 J; 12VAC5-481-1930; 12VAC5-481-2070

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 μCi);
- 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 **12VAC5-481-480 J** or equivalent NRC or another Agreement State requirements.

If molybdenum concentration is measured under **12VAC5-481-1930**, records of molybdenum concentration must be made and must include, for each measured elution of technetium-99m:

- Ratio of the measurements expressed as kBq (μCi) 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 9.20 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: 12VAC5-481-630; 12VAC5-481-750; 12VAC5-481-840; 12VAC5-481-860; 12VAC5-481-1000; 12VAC5-481-1870; 12VAC5-481-1970; 12VAC5-481-2010; 12VAC5-481-2040; 12VAC5-481-2070

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: 12VAC5-481-1970, 12VAC5-481-2010, and **12VAC5-481-2040** require the licensee to take certain safety precautions regarding radiopharmaceutical therapy, manual brachytherapy, or remote afterloader brachytherapy involving patients hospitalized in accordance with **12VAC5-481-1870**. This section does not include teletherapy or GSR outpatient treatments. The precautions described below are to ensure compliance with the exposure limits in **12VAC5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards For Protection Against Radiation'**.

12VAC5-481-2010 and **12VAC5-481-2040** 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. **12VAC5-481-2040** 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 **12VAC5-481-1870**:

- Provide a private room with a private sanitary facility for patients treated with a radiopharmaceutical therapy dosage (**Note: 12VAC5-481-1970** allows for a room shared with another radiopharmaceutical therapy patient);
- Provide a private room for patients implanted with brachytherapy sources (**Note: 12VAC5-481-2010** 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 (**12VAC5-481-1970** and **12VAC5-481-2010**);
- 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 (**12VAC5-481-750** and **12VAC5-481-1970**); and

- Notify the RSO, or his/her designee, and AU as soon as possible if the patient has a medical emergency or dies (**12VAC5-481-1970, 12VAC5-481-2010,** and **12VAC5-481-2040**).

12VAC5-481-750 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 **12VAC5-481-1870** following the dosage administration or implant (e.g., measured exposure rates, combination of measured and calculated exposure rates).

12VAC5-481-840 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 **12VAC5-481-1870**, 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 **12VAC5-481 '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: 12VAC5-481-100; 12VAC5-481-571; 12VAC5-481-910; 12VAC5-481-2070

Criteria: Licensees must maintain records as provided in **12VAC5-481-100; 12VAC5-481-571;** and **12VAC5-481-2070.**

Discussion: The licensee must maintain certain records to comply with **12VAC5-481 '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: 12VAC5-481-740; 12VAC5-481-1090; 12VAC5-481-1100; 12VAC5-481-1110; 12VAC5-481-1150, 12VAC5-481-2080

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 **12VAC5-481-740, 12VAC5-481-1090, 12VAC5-481-1100; 12VAC5-481-1110, 12VAC5-481-1150,** and in **12VAC5-481-2080.** 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 **12VAC5-481 '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 9.23 Reporting

No response is needed during the license process; this issue will be reviewed during inspection.

Item 10: Waste Management

Rule: 12VAC5-481-100; 12VAC5-481-430 G; 12VAC5-481-450 A; 12VAC5-481-570; 12VAC5-481-571; 12VAC5-481-630; 12VAC5-481-720; 12VAC5-481-750; 12VAC5-481-880; 12VAC5-481-910; 12VAC5-481-920; 12VAC5-481-930; 12VAC5-481-940; 12VAC5-481-950; 12VAC5-481-960; 12VAC5-481-970; 12VAC5-481-971; 12VAC5-481-980; 12VAC5-481-990; 12VAC5-481-1000; 12VAC5-481-1050; 12VAC5-481-1060; 12VAC5-481-1090; 12VAC5-481-1100; 12VAC5-481-1710; 12VAC5-481-1870; 12VAC5-481-1890; 12VAC5-481-2070; 12VAC5-481-2980; 12VAC5-481-3690; 49 CFR Parts 170 through 189

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 **12VAC5-481-720**; or
- As authorized under **12VAC5-481-920** through **12VAC5-481-950** and **12VAC5-481-971.**

Appropriate records must be maintained.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with **12VAC5-481-630** 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. **12VAC5-481-910** 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 **12VAC5-481-960**. 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 **12VAC5-481-910, 12VAC5-481-960, 12VAC5-481-971,** or in **12VAC5-481 '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 **12VAC5-481-430 G** is exempt from waste disposal requirements in **12VAC5-481 '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 **12VAC5-481-730** and **12VAC5-481-930,** respectively.
  - Requirements for disposal in the sanitary sewer appear in **12VAC5-481-930**. 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 **12VAC5-481-930**). Make a record of the disposal in accordance with **12VAC5-481-1060**.
  - Limits on permissible concentrations in effluents to unrestricted areas are enumerated in **Table II** of **12VAC5-481-3690**. These limits apply at the boundary of the restricted area. Make a record of the release in accordance with **12VAC5-481-1000** and **12VAC5-481-1050**.
  - 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 (**12VAC5-481-950**). Make a record of the disposal in accordance with **12VAC5-481-1060**.
- 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 **12VAC5-481-940**.
- 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 **12VAC5-481-880** and **12VAC5-481-1890**, 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 **12VAC5-481-1870**. 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 **12VAC5-481-910**. 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 **12VAC5-481-570**. Records of the transfer must be maintained as required by **12VAC5-481-100** and **12VAC5-481-571**.

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. Refer to **12VAC5-491** for fee category and application fees. Enclose fee with the application.

Response from Applicant:

Item 11 License Fees (Refer to **12VAC5-491.**)	
Category:	License Fee Enclosed (For new applications) ☐ Yes ☐ 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 agency will return all unsigned applications for proper signature.**

Response from Applicant:

Item 12 I hereby certify that this application was prepared in conformance with **12VAC5-481 '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 **12VAC5-481-30**, to make a willful false statement or representation on applications or correspondence.
- When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

Appendix A

VDH Form, 'Application for Radioactive Material License for Medical Use'

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

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE FOR MEDICAL USE

The 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 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 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) ( )
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? ☐ 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 another 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 12VAC5-481-1790.

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 another 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 another 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, 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 another 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
☐ Use of Radioactive Material for Certain In-Vitro Clinical or laboratory testing if maximum activity exceeds 200 μCi 12VAC5-481-430(G)	Any	As needed	N/A	N/A
☐ Use of Calibration, Transmission, and Reference Sources not included in 12VAC5-481-1830 (e.g., bone densitometry sources, fluorine-18 calibration sources)	Attach a detailed description of the radioactive material and intended use.		N/A	N/A
☐ Unsealed Radioactive Material for Uptake, Dilution and Excretion Studies for Which a Written Directive is not Required 12VAC5-481-1900	Any	As needed	N/A	N/A
☐ Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is not Required 12VAC5-481-1920	Any	As needed	N/A	N/A
☐ Unsealed Radioactive Material for Which a Written Directive is Required 12VAC5-481-1950	Any		N/A	N/A
☐ Unsealed Radioactive Material for Which a Written Directive is Required Specific radiopharmaceuticals 12VAC5-481-1950	For this type of use attach a detailed description of radiopharmaceutical, form, route of administration and therapeutic use.		N/A	N/A
☐ Sources for Manual Brachytherapy 12VAC5-481-2010	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
☐ Sources for Manual Brachytherapy – Ophthalmic Use Only 12VAC5-481-2010	Sealed Source			
☐ Sealed Sources for Diagnosis 12VAC5-481-2020	Sealed Source			
☐ Sealed Source(s) in a Device for Therapy – Teletherapy Unit 12VAC5-481-2040	Sealed Source			
☐ Sealed Source(s) in a Device for Therapy – Remote Afterloader Unit 12VAC5-481-2040	Sealed Source			

☐ Sealed Source(s) in a Device for Therapy – Gamma Stereotactic Radiosurgery Unit 12 VAC 5-481-2040	Sealed Source			
☐ 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			
☐ 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 12VAC5-481-2010 and 12VAC5-481-2040 (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 VAC5-481-630 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 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.

List the name and license number of organization authorized to perform or analyze leak tests (Specify whether VDH, NRC, or another 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, 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 (12 VAC 5-490)

Category:	Application Fee Enclosed (For new applications): ☐ Yes ☐ No Amount Enclosed: $___

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

RESERVED

Appendix C

VDH Form,
'Certificate of Disposition of Materials'

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

CERTIFICATE OF DISPOSITION OF MATERIALS

Completion of this form is required to complete termination of a Radioactive Material License as outlined in 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 Signatroy

Appendix D

Information Needed for Transfer of Control

Information Needed for Transfer of Control

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

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

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

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

1. Provide a complete description of the transaction (transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact 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 6** 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 **12VAC5-481-450 C** for possession limits requiring financial assurance. The sum of the fractions procedure is also depicted in **Table 6** 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 (**12VAC5-481-450 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 6: 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 **12VAC5-481-1700** 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 VDH and 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)

Documentation of Training and Experience to Identify Individuals on a License as Authorized User (AU), Radiation Safety Officer (RSO), Authorized Medical Physicist (AMP), or Authorized Nuclear Pharmacist (ANP).

A. Experienced AUs, AMPs, ANPs, or RSOs

An applicant or licensee who is adding an experienced AU for medical uses, AMP, ANP, or RSO to its medical use license or application only needs to provide evidence that the individual is listed on a medical use license issued by VDH, the NRC, another Agreement State, a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC master material broad-scope permittee, provided that the individual is authorized for the same types of use(s) requested in the application under review, and the individual meets the recentness of training criteria described in 12VAC5-1790. When adding an experienced ANP to the license, the applicant also may provide evidence that the individual is listed on an NRC or Agreement State commercial nuclear pharmacy license or 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.

B. Applications that Include Individuals for AU, AMP, ANP or RSO Recognition

Applicants should submit the appropriate completed Training, Experience and Preceptor VDH form to show that the individuals meet the correct training and experience criteria in 12VAC5-481, Part VII. For the applicant's convenience, the forms have been separated into eight separate forms. The forms may be found on our website: http://www.vdh.virginia.gov/Epidemiology/RadiologicalHealth/.

There are two primary training and experience routes to qualify an individual as a new AU, AMP, ANP, or RSO. The first is by means of certification by a recognized board and listed on the NRC Web site as provided. Preceptor attestations must also be submitted for all individuals to qualify under 12VAC5-481, Part VII. Additional training may also need to be documented for RSOs, AMPs, and AUs.

The second route is by meeting the structured educational program, supervised work experience, and preceptor attestation requirements in 12VAC5-481, Part VII. In some cases there may be additional training and experience routes for recognized AUs, ANPs, AMPs, or RSOs to seek additional authorizations.

C. Recentness of Training

The required training and experience, including board certification, described in 12VAC5-481, Part VII 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 for physicians 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.

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 **(12VAC5-481-2270)**;
- Basic radiation protection to include concepts of time, distance, and shielding **(12VAC5-481-2270)**;
- Concept of maintaining exposure ALARA **(12VAC5-481-630, 12VAC5-481-2270)**;
- Risk estimates, including comparison with other health risks **(12VAC5-481-2270)**;
- Posting requirements **(12VAC5-481-860)**;
- Proper use of personnel dosimetry (when applicable) **(12VAC5-481-760)**;
- Access control procedures **(12VAC5-481-780, 12VAC5-481-790, 12VAC5-481-840)**;
- Proper use of radiation shielding, if used;
- Patient release procedures **(12VAC5-481-1870)**;
- 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 **(12VAC5-481-1960, 12VAC5-481-2010, 12VAC5-481-2040)**;
- Occupational dose limits and their significance **(12VAC5-481-640)**;
- Dose limits to the embryo/fetus, including instruction on declaration of pregnancy **(12VAC5-481-710)**;
- Worker's right to be informed of occupational radiation exposure **(12VAC5-481-2280)**;
- Each individual's obligation to report unsafe conditions to the RSO **(12VAC5-481-2270)**;
- Applicable regulations, license conditions, information notices, bulletins, etc. **(12VAC5-481-2260)**;

- Where copies of the applicable rules, the VDH license, and its application are posted or made available for examination (**12VAC5-481-2260**);
- Proper recordkeeping required by VDH rules (**12VAC5-481-100, 12VAC5-481-571, 12VAC5-481-2070**);
- Appropriate surveys to be conducted, including surveys of all material leaving radioactive material areas (**12VAC5-481-750, 12VAC5-481-1860**);
- Proper use of required survey instruments (**12VAC5-481-750, 12VAC5-481-1810**);
- Decontamination and release of facilities and equipment (**12VAC5-481-510, 12VAC5-481-1161**);
- Dose to individual members of the public (**12VAC5-481-720**); and
- Licensee's operating procedures (e.g., survey requirements, instrument calibration, waste management, sealed source leak testing) (**12VAC5-481-1710**).

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 (**12VAC5-481-740, 12VAC5-481-1840**);
- Emergency procedures (including emergency response drills) [**12VAC5-481-1960, 12VAC5-481-2010, 12VAC5-481-2040**];
- Operating instructions (**12VAC5-481-1710, 12VAC5-481-2010, 12VAC5-481-2040**);
- Computerized treatment planning system (**12VAC5-481-2040**);
- Dosimetry protocol (**12VAC5-481-2040**);
- Detailed pretreatment quality assurance checks (**12VAC5-481-1710, 12VAC5-481-2040**);
- 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 (**12VAC5-481-1960, 12VAC5-481-2010**);
- Patient control procedures (**12VAC5-481-1960, 12VAC5-481-2010, 12VAC5-481-2040**);
- Visitor control procedures, such as visitors' stay times and safe lines in radiation control areas (patient's room) [**12VAC5-481-1960, 12VAC5-481-2010, 12VAC5-481-2040**];
- 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) [**12VAC5-481-1730**];
- 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) [**12VAC5-481-2010, 12VAC5-481-2040**];
- Size and appearance of different types of sources and applicators (**12VAC5-481-2010, 12VAC5-481-2040**);
- Previous incidents, events, and/or accidents (**12VAC5-481-1960, 12VAC5-481-2010, 12VAC5-481-2040**); 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 **12VAC5-481 'Virginia Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts'** listed in **12VAC5-481-1760**. 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 **12VAC5-481-1760.**

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 **12VAC5-481-1980, 12VAC5-481-1990, 12VAC5-481-2000, 12VAC5-481-2001, 12VAC5-481-2010,** and **12VAC5-481-2040**, 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 **12VAC5-481-1980, 12VAC5-481-2010,** and **12VAC5-481-2040**.

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 (**12VAC5-481-2270**);
- 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) [**12VAC5-481-2270**];

- The applicable provisions of **12VAC5-481 '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) [**12VAC5-481-2270**];
- Responsibility to report promptly to the licensee any condition that may lead to or cause a violation of **12VAC5-481 '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) [**12VAC5-481-2270**];
- Appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material (**12VAC5-481-2270**); and
- Radiation exposure reports that workers may request (**12VAC5-481-2280**).

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 7: 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 **12VAC5-481-630** and **12VAC5-481-1810**. (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 **12VAC5-481-1810**. 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 a 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 (**12VAC5-481-1000** and **12VAC5-481-2070**).
- Before use, perform daily operational-calibration (with a dedicated check source) and battery checks.
- Instrument readings should be within ± 10% of known radiation values at calibration points; however, readings within ± 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 is 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 **12VAC5-481-3690** 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 ± 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 ± 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 **12VAC5-481-630**.

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.
8. Continue to survey the room to ensure that all sources have been found.

Note: A report to VDH may be required pursuant to **12VAC5-481-1090**.

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 **12VAC5-481-1100**.

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: _____ Date: _____
(Signature)

Management Review: _____ Date: _____
(Signature)

Audit History

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

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

C. Were any deficiencies identified during previous audit?

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

Organization and Scope of Program

A. Radiation Safety Officer:

1. If the RSO position has changed, was license amended **(12VAC5-481-1680)**?
2. Does the new RSO meet the agency's training requirements **(12VAC5-481-1750, 12VAC5-481-1780, 12VAC5-481-1790)**?
3. Is the RSO fulfilling all of his/her duties **(12VAC5-481-1700)**?
4. Is the written agreement in place for new RSO **(12VAC5-481-1700)**?

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 **(12VAC5-481-630)**? 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? If so, is financial assurance adequate? **(12VAC5-481-450 C)**
3. Calibration, transmission, and reference sources [**12VAC5-481-1830**]?
    a. Sealed sources manufactured and distributed by a person licensed pursuant to VDH **(12VAC5-481-480)**, NRC, or another equivalent Agreement State regulations who is authorized to redistribute sealed sources that do not exceed 1.11GBq (30 mCi) each **(12VAC5-481-1830)**.
    b. Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceeding 0.555 GBq (15 mCi) [**12VAC5-481-1830**]?
    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 10^3 times the quantities in **12VAC5-481-3730**?
    d. Technetium-99m in amounts as needed? **(12VAC5-481-1830)**
4. Unsealed materials used under **12VAC5-481-1900, 12VAC5-481-1920,** and **12VAC5-481-1950** are:
    a. Obtained from a manufacturer or preparer licensed under **12VAC5-481-480 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 **12VAC5-481-1900, 12VAC5-481-1920,** and **12VAC5-481-1950**, as applicable?

G. Are the sealed sources possessed and used as described in the Sealed Source and Device Registration (SSDR) Certificate **(12VAC5-481-1700, 12VAC5-481-2010, 12VAC5-481-2020,** and **12VAC5-481-2040)**? 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 **(12VAC5-481-1680)**?

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

Radiation Safety Program

A. Minor changes or revision to radiation safety program **(12VAC5-481-1700)**?

B. Records of changes maintained for 5 years **(12VAC5-481-2070)**?

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

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

Use by Authorized Individuals

Compliance is established by meeting at least one criterion under each category.

A. Authorized Nuclear Pharmacist [**12VAC5-481-1770, 12VAC5-481-1780, 12VAC5-481-1790**]

Note: Does not apply to facilities that are registered/licensed by FDA/State Agency as a drug manufacturer with distribution regulated under **12VAC5-481-480 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 (**12VAC5-481-1780, 12VAC5-481-1790, 12VAC5-481-1910, 12VAC5-481-1940, 12VAC5-481-1980, 12VAC5-481-1990, 12VAC5-481-2000, 12VAC5-481-2001, 12VAC5-481-2010, 12VAC5-481-2030, 12VAC5-481-2040**)

_____ 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 [**12VAC5-481-1760, 12VAC5-481-1780, 12VAC5-481-1790**]:

_____ 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 **12VAC5-481-1880** and/or **12VAC5-481-2040**?

B. Compliance with **12VAC5-481-720** has been evaluated and met?

C. Letter signed by management of each client (**12VAC5-481-1880**)?

D. Licensed material was not delivered to client's address (unless the client is licensed to receive radioactive materials) [**12VAC5-481-1880**]?

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 (**12VAC5-481-1880**)?

F. Survey instruments are checked for proper operation before used at each address of use (**12VAC5-481-1880**)?

G. Survey of all areas of use prior to leaving each client address (**12VAC5-481-1880**)?

H. Additional technical requirements for mobile remote afterloaders are per **12VAC5-481-2040**?

Amendments Since Last Audit:

A. Any amendments since last inspection (**12VAC5-481-1680**)?

Notifications Since Last Audit:

A. Any notifications since last audit (**12VAC5-481-1690**)?

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 (**12VAC5-481-1690**)?

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 **12VAC5-481-1900** or **12VAC5-481-1920** use (**12VAC5-481-1690**)?

Training, Retraining, And Instructions to Workers

A. Have workers been provided with all required instructions (**12VAC5-481-1710, 12VAC5-481-1960, 12VAC5-481-2010, 12VAC5-481-2040, 12VAC5-481-2270**)?

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

C. Training program implemented?

1. Operating procedures (**12VAC5-481-1710, 12VAC5-481-1960, 12VAC5-481-2010, 12VAC5-481-2040**)?
2. Emergency procedures (**12VAC5-481-1710, 12VAC5-481-1960, 12VAC5-481-2010, 12VAC5-481-2040**)?
3. Periodic training required and implemented (**12VAC5-481-1960, 12VAC5-481-2010, 12VAC5-481-2040**)?
4. Were all workers who are likely to exceed 1.0 mSv (100 mrem) in a year instructed, and was refresher training provided (**12VAC5-481-2270**)?
5. Was each supervised user instructed in the licensee's written radiation protection procedures and administration of written directives, as appropriate (**12VAC5-481-1710**)?
6. Are initial and periodic training records maintained for each individual for three years (**12VAC5-481-2070**)?
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 (**12VAC5-481-2040**)?

E. Workers cognizant of requirements for:

1. Radiation Safety Program (**12VAC5-481-630, 12VAC5-481-1700**)?
2. Annual dose limits (**12VAC5-481-640, 12VAC5-481-700, 12VAC5-481-710, 12VAC5-481-720**]?
3. VDH Form, 'Occupational Exposure Record Per Monitoring Period'

4. 10% monitoring threshold (**12VAC5-481-760**)?
5. Dose limits to embryo/fetus and declared pregnant worker (**12VAC5-481-710**)?
6. Extreme Danger/Grave Danger Posting (**12VAC5-481-860**)?
7. Procedures for opening packages (**12VAC5-481-900, 12VAC5-481-3091**)?

Note: NRC RIS 8.13 'Instructions Concerning Prenatal Radiation Exposure' is a useful reference.

F. Supervision of individuals by authorized user and/or authorized nuclear pharmacist in accordance with **12VAC5-481-1710**?

Manual Brachytherapy and Unsealed Therapy Training

A. Safety instruction to personnel provided include (**12VAC5-481-1960**):

1. Control of patient and visitors?
2. Routine visitation to patients in accordance with **12VAC5-481-720**?
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 (**12VAC5-481-2070**)?

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 (**12VAC5-481-780, 12VAC5-481-2040**)?

C. Emergency source recovery equipment available (**12VAC5-481-2010, 12VAC5-481-2040**)?

D. Storage areas:

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

E. Therapy unit operation:

1. Unit, console, console keys, and treatment room controlled adequately (**12VAC5-481-840, 12VAC5-481-2040**)?
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 (**12VAC5-481-2040**)?

Dose or Dosage Measuring Equipment

A. Possession, use, calibration, and check of instruments to measure activities of unsealed radionuclides
(12VAC5-481-1800):

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., ±10%)?
5. Records maintained and include required information **(12VAC5-481-2070)**?

B. Determination of dosages of unsealed radioactive material **(12VAC5-481-1820)**?

1. Each dosage determined and recorded prior to medical use **(12VAC5-481-1820)**?
2. Measurement of unit dosages made either by direct measurement or by decay correction **(12VAC5-481-1820)**?
3. For other than unit dosages, measurement made by direct measurement of radioactivity or by combination of radioactivity or volumetric measurement and calculation **(12VAC5-481-1820)**?

C. Licensee uses generators?

1. First eluate after receipt tested for Mo-99 breakthrough **(12VAC5-481-1930)**?
2. No radiopharmaceuticals administered with Mo-99 concentrations over 0.15 μCi per mCi of Tc-99m
(12VAC5-481-1930)?
3. Records of Mo-99 concentrations maintained for 3 years **(12VAC5-481-2070)**?

D. Dosimetry Equipment **(12VAC5-481-2040)**:

1. Calibrated system available for use **(12VAC5-481-2040)**?
2. Calibrated by NIST or an AAPM-accredited lab within previous 2 years and after servicing
or calibrated by inter-comparison per **12VAC5-481-2040**?
3. Calibrated within the previous 4 years **(12VAC5-481-2040)**?
4. Licensee has available for use a dosimetry system for spot-check measurements **(12VAC5-481-2040)**?
5. Record of each calibration, inter-comparison, and comparison maintained **(12VAC5-481-2070)**?

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 **(12VAC5-481-1840)**?
2. Inventory of sealed sources and brachytherapy sources performed semiannually **(12VAC5-481-1840)**?
3. Records maintained for three years **(12VAC5-481-2070)**?

Radiation Survey Instruments

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

1. Appropriate operable survey instruments possessed or available **(12VAC5-481-1800)**
2. Calibrations **(12VAC5-481-1810)**:
   a. Before first use, annually and after repairs?
   b. Within 20% on each scale or decade of interest?
3. Records maintained for three years **(12VAC5-481-2070)**?

B. Radiation surveys performed in accordance with the licensee's procedures and the regulatory requirements **(12VAC5-481-750, 12VAC5-481-1860, 12VAC5-481-2040)**?

1. Daily in all areas where radiopharmaceuticals requiring a written directive are prepared or administered (except patient rooms) [**12VAC5-481-1860**]?
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 sources(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry **(12VAC5-481-2040)** and records maintained **(12VAC5-481-2070)**?
   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 **(12VAC5-481-720)**?

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

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

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

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

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

Patient Release

A. Individuals released when TEDE less than 5 mSv (500 mrem) (**12VAC5-481-1870**)?

B. Instructions to the released individual, including breast-feeding women, include required information (**12VAC5-481-1870**)?

C. Release records maintained for three years (**12VAC5-481-2070**)?

D. Records of instructions given to breast-feeding women maintained, if required, for three years (**12VAC5-481-2070**)?

Radiopharmaceutical Therapy

A. Safety precautions implemented to include patient facilities, posting, stay times, patient safety guidance, release, and contamination controls (**12VAC5-481-1970**)?

B. RSO and AU promptly notified if patient died or had a medical emergency (**12VAC5-481-1970**)?

Brachytherapy

A. Safety precautions implemented to include patient facilities, posting, stay times, and emergency response equipment (**12VAC5-481-2010**)?

B. Survey immediately after implant (**12VAC5-481-2010**)?

C. Patients surveyed immediately after removing the last temporary implant source (**12VAC5-481-2010**)?

D. RSO and AU promptly notified if patient died or had a medical emergency (**12VAC5-481-2010**)?

E. Records maintained for three years (**12VAC5-481-2070**)?

Radioactive Waste

A. Disposal:

1. Decay-in-storage (**12VAC5-481-1890**)?
2. Procedures followed (**12VAC5-481-1890**)?
3. Labels removed or defaced (**12VAC5-481-880, 12VAC5-481-1890**)?

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

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

D. Records maintained (**12VAC5-481-100, 12VAC5-481-571, 12VAC5-481-1000, 12VAC5-481-1060, 12VAC5-481-2070**)?

E. Effluents:

1. Release to sanitary sewer (**12VAC5-481-930**)?
   a. Material is readily soluble or readily dispersible (**12VAC5-481-930**)?
   b. Monthly average release concentrations do not exceed **12VAC5-481-3690, Table III** values?
   c. No more than 185 GBq (5.0 Ci) of H-3, 37GBq (1.0 Ci) of C-14 and 37 GBq (1.0 Ci) of all other radionuclides combined released in a year (**12VAC5-481-930**)?
   d. Procedures to ensure representative sampling and analysis implemented (**12VAC5-481-630**)?
2. Release to septic tanks (**12VAC5-481-930**)?
   a. Within unrestricted limits **12VAC5-481-3690, Table III** and **12VAC5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation'**?
3. Waste incinerated?
   a. License authorizes (**12VAC5-481-940**)?
   b. Directly monitor exhaust?
   c. Airborne releases evaluated and controlled (**12VAC5-481-730, 12VAC5-481-750**)?
4. Air effluents and ashes controlled (**12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-750, 12VAC5-481-910**)?
   a. Air effluent less than 10 mrem constraint limit (**12VAC5-481-630**)?
   b. If no, reported appropriate information to VDH.
      i. Corrective actions implemented and on schedule?
   c. Description of effluent program:
      i. Monitoring system hardware adequate?
      ii. Equipment calibrated, as appropriate?
      iii. Air samples/sampling technique (i.e., charcoal, HEPA, etc.) analyzed with appropriate instrumentation?

Note: Useful references are NRC Inspection Procedure 87102 and NRC Regulatory Guide 8.37. The are available at www.nrc.gov.

F. Waste storage:

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

G. Waste disposal:

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

_____.

H. Records of surveys and material accountability are maintained (**12VAC5-481-1000, 12VAC5-481-1060, 12VAC5-481-2070**)?

Receipt and Transfer of Radioactive Material

A. Describe how packages are received and by whom.

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

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

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

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

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

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

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

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

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

A. Shipments are:

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

B. 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 **(12VAC5-481-2040)**?

B. Needed service arranged for as identified during the inspection?

C. Service performed by persons specifically authorized to do so **(12VAC5-481-2040)**?

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 **(12VAC5-481-2040)**?

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 **(12VAC5-481-2040)**?

D. Whenever spot-checks indicate output differs from expected by ±5% **(12VAC5-481-2040)**?

E. After source exchange, relocation, major repair or modification **(12VAC5-481-2040)**?

F. Performed with properly calibrated instrument **(12VAC5-481-2040)**?

G. Includes

1. For teletherapy:
    a. Output measured within ±3% of expected for the range of field sizes, range of distances (**12VAC5-481-2040**)?
    b. Coincidence of radiation field and field light localizer (**12VAC5-481-2040**)?
    c. Uniformity of radiation field and beam angle dependence (**12VAC5-481-2040**)?
    d. Timer accuracy and linearity over the range of use (**12VAC5-481-2040**)?
    e. On-off error (**12VAC5-481-2040**)?
    f. Accuracy of all measuring and localization devices (**12VAC5-481-2040**)?
2. For remote afterloaders:
    a. Output measured within ±5% of expected (**12VAC5-481-2040**)?
    b. Source positioning accuracy within ±1 millimeter (**12VAC5-481-2040**)?
    c. Source retraction with backup battery upon power failure (**12VAC5-481-2040**)?
    d. Length of source transfer tubes (**12VAC5-481-2040**)?
    e. Timer accuracy and linearity over the typical range of use (**12VAC5-481-2040**)?
    f. Length of the applicators (**12VAC5-481-2040**)?
    g. Function of source transfer tubes, applicators, and transfer tube-applicator interfaces (**12VAC5-481-2040**)?
    h. Autoradiograph quarterly of the LDR source(s) to verify source(s) arrangement and inventory (**12VAC5-481-2040**)?
3. For gamma stereotactic radiosurgery:
    a. Output measured within ±3% of expected (**12VAC5-481-2040**)?
    b. Helmet factors (**12VAC5-481-2040**)?
    c. Isocenter coincidence (**12VAC5-481-2040**)?
    d. Timer accuracy and linearity over the range of use (**12VAC5-481-2040**)?
    e. On-off error (**12VAC5-481-2040**)?
    f. Trunnion centricity (**12VAC5-481-2040**)?
    g. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off (**12VAC5-481-2040**)?
    h. Helmet microswitches (**12VAC5-481-2040**)?
    i. Emergency timing circuit (**12VAC5-481-2040**)?
    j. Stereotactic frames and localizing devices (trunnions) (**12VAC5-481-2040**)?

H. Output corrected mathematically for decay (**12VAC5-481-2040**)?

I. Records maintained for three years (**12VAC5-481-2070**)?

Periodic Spot Checks For Therapeutic Devices

A. Performed at required frequency (**12VAC5-481-2040**)?

B. Procedures established by authorized medical physicist (**12VAC5-481-2040**)?

C. Procedures are being followed?

D. Authorized medical physicist reviews results within 15 days (**12VAC5-481-2040**)?

E. Performed with properly calibrated instrument (**12VAC5-481-2040**)?

F. Output and safety spot checks include:

1. For teletherapy:
    a. Timer accuracy and linearity over the range of use (**12VAC5-481-2040**)?
    b. On-off error (**12VAC5-481-2040**)?
    c. Coincidence of radiation field and field light localizer (**12VAC5-481-2040**)?
    d. Accuracy of all measuring and localization devices (**12VAC5-481-2040**)?
    e. The output for one typical set of operating conditions (**12VAC5-481-2040**)?
    f. Difference between measured and expected output (**12VAC5-481-2040**)?
    g. Interlock systems (**12VAC5-481-2040**)?
    h. Beam stops (**12VAC5-481-2040**)?
    i. Source exposure indicator lights (**12VAC5-481-2040**)?
    j. Viewing and intercom systems (**12VAC5-481-2040**)?
    k. Treatment room doors, inside and out (**12VAC5-481-2040**)?
    l. Electrical treatment doors with power shut off (**12VAC5-481-2040**)?
2. For remote afterloaders:
    a. Interlock systems (**12VAC5-481-2040**)?
    b. Source exposure indicator lights (**12VAC5-481-2040**)?
    c. Viewing and intercom systems, except for LDR (**12VAC5-481-2040**)?
    d. Emergency response equipment (**12VAC5-481-2040**)?
    e. Radiation monitors used to indicate source position (**12VAC5-481-2040**)?
    f. Timer accuracy (**12VAC5-481-2040**)?
    g. Clock (date and time) in the unit's computer (**12VAC5-481-2040**) accurate?
    h. Decayed source(s) activity in the unit's computer (**12VAC5-481-2040**)?
3. For gamma stereotactic radiosurgery:
    a. Treatment table retraction mechanism (**12VAC5-481-2040**)?
    b. Helmet microswitches (**12VAC5-481-2040**)?
    c. Emergency timing circuits (**12VAC5-481-2040**)?
    d. Stereotactic frames and localizing devices (**12VAC5-481-2040**)?
    e. The output for one typical set of operating conditions (**12VAC5-481-2040**)?
    f. Difference between measured and expected output (**12VAC5-481-2040**)?
    g. Source output compared against computer calculation of output (**12VAC5-481-2040**)?
    h. Timer accuracy and linearity over the range of use (**12VAC5-481-2040**)?
    i. On-off error (**12VAC5-481-2040**)?
    j. Trunnion centricity (**12VAC5-481-2040**)?
    k. Interlock systems (**12VAC5-481-2040**)?
    l. Source exposure indicator lights (**12VAC5-481-2040**)?
    m. Viewing and intercom systems (**12VAC5-481-2040**)?
    n. Timer termination (**12VAC5-481-2040**)?
    o. Radiation monitors used to indicate room exposures (**12VAC5-481-2040**)?
    p. Emergency off buttons (**12VAC5-481-2040**)?

G. Licensee promptly repaired items found to be not operating properly and did not use unit until repaired, if required **(12VAC5-481-2040)**?

H. Records maintained for three years **(12VAC5-481-2070)**?

Installation, Maintenance, and Repair of Therapy Devices

A. Only authorized individuals perform installations, maintenance, adjustment, repair, and inspections **(12VAC5-481-2040)**? Name of organization/individual:_____.

B. Records maintained for three years **(12VAC5-481-2070)**?

Operating Procedures For Therapy Devices

A. Instructions on location of emergency procedures and emergency response telephone numbers are posted at the device console **(12VAC5-481-2040)**?

B. Copy of the entire procedures physically located at the device console **(12VAC5-481-2040)**?

C. Procedures include:

1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions **(12VAC5-481-2040)**?
2. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure **(12VAC5-481-2040)**?
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 **(12VAC5-481-2040)**?

D. Radiation survey of patient is performed to ensure source is returned to shielded position **(12VAC5-481-2040)**?

E. Records of radiation surveys maintained for 3 years **(12VAC5-481-2070)**?

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 **(12VAC5-481-2040)**?
2. Physically present throughout all patient treatments with a gamma stereotactic radiosurgery device **(12VAC5-481-2040)**?

Personnel Radiation Protection

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

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

C. External Dosimetry

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

D. Internal Dosimetry:

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

E. Review of Records and Reports:

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

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

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

Confirmatory Measurements

Detail location and results of confirmatory measurements.

Medical Events

If medical events (criteria as in **12VAC5-481-2080**) have occurred since the last audit, evaluate the incident(s) and procedures for implementing and administering written directives using the existing guidance.

A. Event date _____ Information Source _____

B. Notifications

1. Virginia Department of Health
2. The referring physician
3. Patient in writing/by telephone
4. If notifications did not occur, why not?

C. Written Reports **(12VAC5-481-2080)**:

1. Submitted to the agency within 15 days?

Notification and Reports

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

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

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

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

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

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

Posting and Labeling

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

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

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

Recordkeeping for Decommissioning

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

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

Information Notices and Regulatory Issue Summaries

A. VDH Information Notices, etc., received?

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

Special License Conditions or Issues

A. Special license conditions or issues to be reviewed:

B. Evaluation:

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 **12VAC5-481-630** and **12VAC5-481 '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 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 **12VAC5-481-640**. 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 **12VAC5-481-10.** 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 (**12VAC5-481-750**).

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

12VAC5-481-630 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, **12VAC5-481-630** 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 **12VAC5-481-640** 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 **12VAC5-481-10**, the deep dose exposure (DDE) to the whole body is considered to be at a tissue depth of 1 cm (1000 mg/cm^2), shallow-dose equivalent to the skin or extremities at 0.007 cm (7 mg/cm^2), and eye dose equivalent at 0.3 cm (300 mg/cm^2). 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 **12VAC5-481-760** 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 **12VAC5-481-760** 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:
  - 0.1 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 **12VAC5-481-750**. 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 (**12VAC5-481-640**). 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.

12VAC5-481-1040 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 **12VAC5-481-2280** 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 8** (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 8** (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 8: 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 8** 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 8** 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 or additional safety measures are needed to reduce exposures. Evaluate in the context of the 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-establish the Investigational Level II to a level above that listed in **Table 8**.

Declared Pregnancy and Dose to Embryo/Fetus

12VAC5-481-710 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).

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. **12VAC5-481 '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 μCi/ml that, if an occupational worker were to be continuously exposed to for 2,000 hours (1 year), would result in either a committed effective dose equivalent (CEDE) of 5 rem (0.05 Sv) to the whole body or a committed dose equivalent (CDE) 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 **12VAC5-481-3690.**

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 CEDE of 5 rem (0.05 Sv) or a CDE 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. **12VAC5-481-3690,** 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 **12VAC5-481-3690,** 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 **12VAC5-481-1000** and **12VAC5-481-1040**. 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 **12VAC5-481-640**, the external and internal doses must be summed if required to monitor both under **12VAC5-481-760**.

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 found at www.nrc.gov.

Appendix M

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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 **12VAC5-481-630**.

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 1×10^{-5} µCi/ml in restricted areas and 3×10^{-7} µCi/ml in unrestricted areas. For other gases, see **12VAC5-481-3690**; 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 **12VAC5-481-1100**.

Use **Table 9** 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 9 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: NRCP 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 **12VAC5-481-900**.

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 **12VAC5-481-3770** (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 **12VAC5-481-900**.

VDH and the final delivery carrier must be notified if the following conditions apply:

- Removable radioactive surface contamination exceeds the limits of **12VAC5-481-3080** (i.e. 22 dpm/cm^2 of beta or gamma emitting photons or 2.2 dpm/cm^2 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 **12VAC5-481-10**. (**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 **12VAC5-481-10** and **12VAC5-481-3770**. (**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, notify RSO immediately.
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(T1) 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 **12VAC5-481-430 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 μCi) 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 ± 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 **12VAC5-481-2070** 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 **12VAC5-481-740**. 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 **12VAC5-481-630, 12VAC5-481-750,** and **12VAC5-481-1860**.

Ambient Radiation Level Surveys

Procedures for ambient radiation level surveys (reference **12VAC5-481-630, 12VAC5-481-750, 12VAC5-481-1860**):

- 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).
- **12VAC5-481-720** 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 **12VAC5-481-720** 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 μCi).
  - 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 μCi 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 10.**

Table 10 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 10 and 11** for unrestricted areas (e.g., 200 dpm/100 cm^2 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.
- If contamination is found above the applicable limits, 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 **12VAC5-481-1100**.
- 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 10**. Contamination found in unrestricted

areas and on personal clothing will be immediately decontaminated to background levels.

Table 11 Surface Contamination Levels in Restricted Areas (dpm/100 cm^2)

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 12 Surface Contamination Levels in Unrestricted Areas (dpm/100 cm^2)

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 contaminantion should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.
4. The maximum contamination level applies to an area of not more than 100 cm^2.
5. The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.
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 10 and 11**.

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 9**)
- 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 13 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 T1-204
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 14 Classification of Laboratories for Alternate Survey Frequency

	Survey Frequency Category		
Group	**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 15 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 **12VAC5-481-1720** and **12VAC5-481-1730**.

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 **12VAC5-481-1730** will be met.

The WD must be prepared for any administration of I-131 sodium iodide greater than 1.11 MBq (30 μCi), any therapeutic dosage of a radiopharmaceutical, and any therapeutic dose of radiation from radioactive material. The WD must contain the information described in **12VAC5-481-1720** and be retained in accordance with **12VAC5-481-2070**.

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 **12VAC5-481-1720** requires, or would require, a written directive (as defined in **12VAC5-481-10**), the licensee shall develop, implement, and maintain written procedures for WDs to meet the requirements and/or objectives of **12VAC5-481-1720, 12VAC5-481-1730,** and **12VAC5-481-1820**, outlined below:

- Have an authorized user date and sign a written directive prior to the administration that includes the information in **12VAC5-481-1720**, 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 **12VAC5-481-1720** and **12VAC5-481-1730**:

- 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 **12VAC5-481-1720** and **12VAC5-481-1730** 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 on the written directive: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose) as required by **12VAC5-481-1720**. 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 **12VAC5-481-1760**) using a dosimetry system other than the one that was used during the full calibration (the dosimetry system will meet the requirements specified in **12VAC5-481-2040**); 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 **12VAC5-481-1730**, 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 **12VAC5-481-2080**. Also notify the referring physician and the patient as required by **12VAC5-481-2080**.

Note: The telephone number of the VDH Office is (804) 864-8150, daytime; (804) 674-2400 or (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 **12VAC5-481-630, 12VAC5-481-720,** and **12VAC5-481-1850**.

- 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 **12VAC5-481-1860** (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 **12VAC5-481-880** and **12VAC5-481-1850**. 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 **12VAC5-481-880** and **12VAC5-481-1850**. 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 **12VAC5-481-3700**, the syringe or vial need only be labeled to identify the radioactive drug (**12VAC5-481-1850**). 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 (**12VAC5-481-1820**).
- Do not use a dosage if it does not fall within the prescribed dosage range or if it varies more than ±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 (**12VAC5-481-1730**).

- 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

12VAC5-481-1870, 'Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material,' of **12VAC5-481 '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, $(1\text{-}e^{-0.693t/Tp})$ 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

Licensees 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 **12VAC5-481-1870**, licensees may release patients from licensee control if the activity administered is no greater than the activity in Column 1 of **Table 16**. The activities in **Table 16** 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 **12VAC5-481-1720** and **12VAC5-481-1820**.

If the activity administered exceeds the activity in Column 1 of **Table 16**, the licensee may release the patient when the activity has decayed to the activity in Column 1 of **Table 16**. In this case, **12VAC5-481-1870** 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 16** 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 16** is administered, the licensee can demonstrate compliance with the regulation by maintaining, for agency 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 16** 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 16** 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 **12VAC5-481-1870**.

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 16**, 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 16** for that radionuclide. In this case, however, **12VAC5-481-1870** requires a record because the release is based on considering shielding by tissue.

If a radionuclide not listed in **Table 16** 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 **12VAC5-481-1870**. 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 $\Gamma Q/10{,}000\ cm^2$.

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 **12VAC5-481-1870**, 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 16** 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 **12VAC5-481-1870**. 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 **12VAC5-481-1870**.

Supplement B contains procedures for performing patient-specific dose calculations, and it describes how various factors may be considered in the calculations.

Table 16 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 **12VAC5-481-1870**, 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 **12VAC5-481-1870**.

(**Note:** VDH does not intend to enforce patient compliance with the instructions nor is it the licensee's responsibility to do so.)

U.2.1 Activities and Dose Rates Requiring Instructions

Based on **12VAC5-481-1870** 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. Column 1 of **Table 17** 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 17** 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 17** 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 **12VAC5-481-1870** 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. 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 18** 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 18** 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 18** are commonly used in medical diagnosis and treatment.

If a radiopharmaceutical not listed in **Table 18** 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 17 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 NRC NUREG-1492.

Table 18 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 *In Vivo* Labeling	400	10	2000	50	6 hours for 740 MBq (20 mCi)
Tc-99m Red Blood Cell *In Vitro* 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 **12VAC5-481-1870**, 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 **12VAC5-481-1870**.

The requirement of **12VAC5-481-1870** 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 16**; 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 **12VAC5-481-1870**. 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 **12VAC5-481-1870**, 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 **12VAC5-481-1870**. Column 2 of **Table 18** 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 19 summarizes the criteria for releasing patients and the requirements for providing instructions and maintaining records.

Table 19 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 16**	Yes, if administered activity > Column 1 of **Table 17**	No
	Retained activity	Retained activity = Column 1 of **Table 16**	Yes, if retained activity > Column 1 of **Table 17**	Yes
	Measured dose rate	Measured dose rate = Column 2 of **Table 16**	Yes, if dose rate > Column 2 of **Table 17**	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 18** **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 18** **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 **12VAC5-481-1870**, the methods described in this appendix will be used in the evaluation of a licensee's compliance with **12VAC5-481-1870**.

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 Medicin*e, edited by S. Treves, Springer Verlag, New York, 1995.
- 'Guidelines for Patients Receiving Radioiodine Treatment,' *Society of Nuclear Medicin*e, 1987. This pamphlet may be obtained from the Society of Nuclear Medicine, 136 Madison Avenue, New York, NY 10016-6760.

Supplement A

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

Table 20 Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine

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 ^{125}I and ^{192}Ir 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 16** of this appendix 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 **12VAC5-481-1870**. 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 16

In **Table 16** 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 16** 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 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 = ∞) 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.

$$D(\infty) = \frac{34.6(2.2R \cdot cm^2 / mCi \cdot hr)(60mCi)(8.04d)(0.125)}{(100\,\text{cm})^2}$$

$$D\ (\infty) = 4.59\ \text{mSv}\ (0.459\ \text{rem})$$

Since the dose is less than 5 mSv (0.5 rem), the patient may be released, but **12VAC5-481-1870** 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 **12VAC5-481-1870**, 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 **12VAC5-481-1870**. 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
Tp = 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:

$$D(\infty) = \frac{34.6\,\Gamma\,Q_0}{(100\,\mathrm{cm})^2}\{E_1\,T_p\,(0.8)(1 - e^{-0.693(0.33)/T_p}) + e^{-0.693(0.33)/T_p}\,E_2\,F_1\,T_{1eff} + e^{-0.693(0.33)/T_p}\,E_2\,F_2\,T_{2eff}\}$$

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_{1eff}, F_2, and T_{2eff} are shown in **Table 21** 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 **12VAC5-481-1870** 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 20**. The uptake fractions and effective half-lives are from **Table 21**. 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 mSv (0.340 rem)

Table 21 Uptake Fractions and Effective Half-Lives for Iodine-131 Treatments

Medical Condition	Extrathyroidal Component		Thyroidal Component	
	Uptake Fraction F_1	Effective Half-Life T_{1eff} (day)	Uptake Fraction F_2	Effective Half-Life T_{2eff} (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 **12VAC5-481-1870**, 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 20**, and **Table 21**, 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:

$$D(\infty) = \frac{(34.6)(2.2)(55)}{(100\,\text{cm})^2}\{(0.75)(8.04)(0.8)(1 - e^{-0.693(0.33)/8.04})$$
$$+e^{-0.693(0.33)/8.04}(0.25)(0.20)(0.32) + e^{-0.693(0.33)/8.04}(0.25)(0.80)(5.2)\}$$

$$D(\infty) = 4.86 \text{ mSv } (0.486 \text{ rem})$$

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 **12VAC5-481-1870** 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:

$$D_i = (33 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$
$$D_i = 0.17 \text{ mSv } (0.017 \text{ rem})$$

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:

$$D_i = (150 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$
$$D_i = 0.80 \text{ mSv } (0.08 \text{ rem})$$

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 **12VAC5-481 '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 **12VAC5-481-2040**.

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 **12VAC5-481-1880**, 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 **12VAC5-481-1880** and **12VAC5-481-2070**. Additionally, as required by **12VAC5-481-1880**, the licensee will survey to ensure compliance with the requirements in **12VAC5-481 '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 **12VAC5-481-450** and **12VAC5-481-500**, 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 **12VAC5-481-720.** 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 **12VAC5-481-640.**

- 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 **12VAC5-481-720.**
  - 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 **12VAC5-481-720**. 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 **12VAC5-481-1880**, that the mobile medical service licensee has full control of the treatment room during radioactive material use for each client.

- **12VAC5-481-1880** 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 **12VAC5-481-1880**, 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 **12VAC5-481-2040**.

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 **12VAC5-481-1710**, 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 **12VAC5-481-570** and **12VAC5-481-571**, 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 **12VAC5-481-2270**, you will instruct supervised individuals in your written radiation protection procedures, written directive procedures, VDH 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 **12VAC5-481-1690**. 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 **12VAC5-481-1960, 12VAC5-481-2010, 12VAC5-481-2040,** and **12VAC5-481-2270** (as applicable). The training for these individuals will include, at a minimum, VDH and 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 **12VAC5-481-1880**, 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 **12VAC5-481-630.** 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: 7:30 a.m. to 4:30 p.m. (804) 864-8150; After hours: (804) 674-2400 or (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 **12VAC5-481-1100**, 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 **12VAC5-481-930**. 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 agency 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 **12VAC5-481-640** and **12VAC5-481-720**, 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 and the additional spot checks required by **12VAC5-481-2040** 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 **12VAC5-481-2070**, showing the results of the above safety checks for agency 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 VDH and 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/

Hazard Communications for Class 7 (Radioactive) Materials

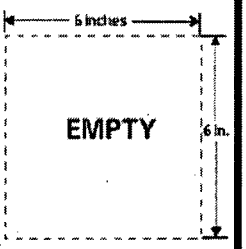
Labeling Packages (49 CFR 172.400-450)

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

Placement of Radioactive Labels

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

Determination of Required Label

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

Content on Radioactive Labels

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

Some Special Considerations/Exceptions for Labeling Requirements

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

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 **12VAC5-481-630**, **12VAC5-481-910**, and **12VAC5-481-1890**.

Procedure for Decay-In-Storage

12VAC5-481-1890 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 **12VAC5-481-1890**);
  - 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 **12VAC5-481-2980** and **12VAC5-481 '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 **12VAC5-481-100** and **12VAC5-481-571**.

Procedure for Return of Licensed Material to Authorized Recipients

Perform the following steps when returning licensed material to authorized recipients:

- In accordance with **12VAC5-481-570**, confirm that persons are authorized to receive radioactive material prior to transfer (e.g., obtain a copy of the transferee's VDH, NRC, or another 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 **12VAC5-481-100** and **12VAC5-481-571**.

Appendix Y

Recordkeeping Requirements

Record	Survey Requirement	Record Requirement	Retention Period
Results of surveys and calibrations	12VAC5-481-750; 12VAC5-481-900	12VAC5-481-1000	3 years
Results of surveys to determine dose from external sources		12VAC5-481-1000	Duration of license
Results of measurements and calculations used to determine individual intakes		12VAC5-481-1000	Duration of license
Results of air samplings, surveys and bioassays	12VAC5-481-830	12VAC5-481-1000	Duration of license
Results of measurements and calculations used to evaluate the release of radioactive effluents to the environment		12VAC5-481-1000	Duration of license
Determination of prior occupational dose		12VAC5-481-1020	Duration of license
Planned special exposure	12VAC5-481-690	12VAC5-481-1030	Duration of license
Individual monitoring results	12VAC5-481-760	12VAC5-481-1040	Duration of license
Dose to individual members of the public	12VAC5-481-730	12VAC5-481-1050	Duration of license
Waste Disposal	12VAC5-481-910	12VAC5-481-1060	Duration of license
Receipt, transfer and disposal of radioactive material	12VAC5-481-570	12VAC5-481-100; 12VAC5-481-571	Duration of possession and 3 years thereafter
Authority and responsibilities of radiation protection program	12VAC5-481-1700	12VAC5-481-2070	5 years
Radiation protection program changes	12VAC5-481-1700	12VAC5-481-2070	5 years
Written directives	12VAC5-481-1720	12VAC5-481-2070	3 years
Calibrations of instruments used to measure activity of unsealed radioactive material	12VAC5-481-1800	12VAC5-481-2070	3 years
Radiation survey instruments calibrations	12VAC5-481-1810	12VAC5-481-2070	3 years
Dosages of unsealed radioactive material for medical use	12VAC5-481-1820	12VAC5-481-2070	3 years
Leak tests and inventory of sealed sources and brachytherapy sources	12VAC5-481-1840	12VAC5-481-2070	3 years
Surveys for ambient radiation exposure rate	12VAC5-481-1860	12VAC5-481-2070	3 years
Release of individuals containing unsealed radioactive material or implants containing radioactive material	12VAC5-481-1870	12VAC5-481-2070	3 years

Appendix Z

Reporting Requirements

EVENT	TELEPHONE NOTIFICATION	WRITTEN REPORT	12VAC5-481 REQUIREMENT
Reports to individuals workers	None	Annually	**12VAC5-481-2280**
Reports to former individual workers	None	Upon request	**12VAC5-481-2280**
Reports to worker terminating employment	None	Upon request	**12VAC5-481-2280**
Theft or lost of material	Immediate	30 days	**12VAC5-481-1090**
Whole body dose greater than 0.25 Sv (25 rems)	Immediate	30 days	**12VAC5-481-1100; 12VAC5-481-1110**
Extremity dose greater than 2.5 Sv (250 rems)	Immediate	30 days	**12VAC5-481-1100; 12VAC5-481-1110**
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	**12VAC5-481-1100; 12VAC5-481-1110**
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	**12VAC5-481-1100; 12VAC5-481-1110**
Doses in excess of specified criteria	None	30 days	**12VAC5-481-1110**
Levels of radiation or concentrations of radioactive material in excess of specified criteria	None	30 days	**12VAC5-481-1110**
Planned special exposure	None	30 days	**12VAC5-481-1120**
Report to individuals of exceeding dose limits	None	30 days	**12VAC5-481-1110**
Report of individual monitoring	None	Annually	**12VAC5-481-1130**
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	Immediate	30 days	**12VAC5-481-1100**
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	**12VAC5-481-1100**
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	**12VAC5-481-1100**
Licensee permits individual to work as AU, ANP, or AMP	None	30 days	**12VAC5-481-1690**

Commonwealth of Virginia
Radiation Protection Regulatory Guide

Guidance for Licenses of Broad Scope

EPI-720 H

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

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

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

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

Appendix C through V provides examples, models and additional information that can be used when completing the application.

It typically takes 60-90 days for a license to be processed and issued if the application is complete. When submitting the application be sure to include the appropriate application fee listed in **12VAC5-491** for a Broad Scope license.

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

- Complete the application VDH Form 'Application for Radioactive Material License for Broad Scope' (**Appendix A**). See 'Contents of Application' of the guide for additional information.
- Include any additional attachments.

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

  Please identify all attachments with the applicant's name and license number (if a renewal).
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original signed application along with attachments (if any) and if possible a copy on a diskette or CD (Microsoft Word is preferred).
- Submit the application fee.
- Retain one copy of the licensee application and attachments (if any) for your future reference. You will need this information because the license will require that radioactive material be possessed and used in accordance with statements, representation, and procedures provided in the application and supporting documentation.

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

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LIST OF APPENDICES

LIST OF TABLES

ABBREVIATIONS

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

PURPOSE OF GUIDE

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

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

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

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

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

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

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

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

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

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

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

to the use of radioactive material under the Type A broad scope license (e.g., use of source material in subcritical assemblies and special nuclear material in cardiac pacemakers).

Types B and C broad scope licenses are restricted in their possession of radioactive material by **12VAC5-481-470** and **12VAC5-481-3760.** Type B and Type C licensees who require materials not specified in **12VAC5-481-3760** will need to: (1) develop Type A broad scope programs, which would require a license amendment; or (2) carry these additional materials under a separate specific license of limited scope. The latter option would require that the licensee review the base VAREG related to the specific use of this material and submit the information required by the license reviewer as described in that document. For example, applicants who require materials not specified in **12VAC5-481-3760** for the purposes of research and development should review VAREG, 'Guidance For Academic, Research and Development, and Other Licenses of Limited Scope' and submit the information described therein. Licensees are reminded that changes to the specific license of limited scope require amendment of the license.

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

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

licensing process. VDH will continue to allow licensees to build in this type of program flexibility.

Through license condition, VDH will provide even greater flexibility to Type A broad scope licensees who have developed an adequate radiation safety program oversight structure. Type A broad scope licensees and applicants for Type A broad scope license who specify the duties and responsibilities of management, the RSC, and the RSO, including: (1) review and approval of program and procedural changes by the RSC; (2) implementation of program and procedural changes; (3) audit of licensed operations to determine compliance; and (4) taking appropriate actions when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence, will be authorized, through use of the license condition listed below, to make some program changes and to revise some procedures previously approved by VDH without amendment of the license as long as the program change or revised procedure:

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

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

Type A Broad Scope License Condition Used to Grant Additional Flexibility:

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

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

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

-The licensees staff is trained in the revised procedures prior to implementation; and
-The licensees audit program evaluates the effectiveness of the change and its implementation.

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

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

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

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

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

- **Response from Applicant** -- provides suggested response(s), offers the option of an alternative reply, or indicates that no response is needed on that topic during the licensing process.

As indicated on the application, the answers to some items are to be provided on separate sheets of paper and submitted with the completed VDH Form, 'Application for Radioactive Material License for Broad Scope' (**Appendix A**).

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

LICENSES

Applicants should study this document, related guidance, and all applicable regulations carefully before completing the VDH Form, 'Application for Radioactive Material License for Broad Scope'. VDH expects licensees to provide requested information on specific aspects of their proposed radiation 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

12VAC5-481-630, Radiation protection programs, states that *"each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities"* and *"the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are...ALARA."* This section also requires that licensees review the content of the radiation protection program and its implementation annually.

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

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

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

WHO REGULATES FACILITIES IN THE COMMONWEALTH OF VIRGINIA?

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

Table 1: Who Regulates the Activity?

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

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

MANAGEMENT RESPONSIBILITY

VDH recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. VDH also believes that consistent compliance with **12VAC5-481 'Virginia Radiation Protection Regulations'** provides reasonable assurance that licensed activities will be conducted safely. VDH has found that effective management is key to a well-run radiation safety program. Management refers to a senior-level manager who has responsibility for overseeing licensed activities.

To ensure adequate management involvement, a management representative must sign the submitted application acknowledging management's commitments and responsibility for all the following:

- Radiation safety, security and control of radioactive materials, and compliance with **12VAC5-481 'Virginia Radiation Protection Regulations'**;
- Completeness and accuracy of the radiation safety records and all information provided to VDH;
- Knowledge about the contents of the license and application;
- Committing adequate resources (including space, equipment, personnel, time and if needed, contractors) to the radiation protection program to ensure that public and worker safety is protected from radiation hazards and compliance with the rule is maintained;
- Selecting and assigning a qualified individual to serve as the Radiation Safety Officer (RSO) for their licensed activities.

APPLICABLE RULE

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

The following parts of **12VAC5-481 'Virginia Radiation Protection Regulations'** contain requirements applicable to the use of licensed material by broad scope licensees:

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

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

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

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

HOW TO FILE

Applicants for a materials license should do the following:

- Be sure to use the current guidance from VDH in preparing an application.
- Complete VDH Form, 'Application for Radioactive Material License for Broad Scope' (**Appendix A**).
- For each separate sheet, other than submitted with the application, identify and key it to the item number on the application, or the topic to which it refers.
- Submit all documents on 8 ½ x 11 inch paper.
- Avoid submitting proprietary information unless it is absolutely necessary.
- 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.

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

WHERE TO FILE

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

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

LICENSE FEES

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

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

Direct all questions about VDH's fees or completion of **Item 15** of VDH Form, 'Application for Radioactive Material License for Broad Scope' (**Appendix A**) to: **Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, Virginia 23219 or (804) 864-8150**.

CONTENTS OF AN APPLICATION

Item 1: Type of Application

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

Response from Applicant:

Item 1 Type Of Application (Check one box)
☐ New License ☐ Renewal License Number _____

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):) - x

Note: VDH 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: 12VAC5-481-330; 12VAC5-481-500

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

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

- Radioactive materials are possessed, used, or controlled only by persons who have valid VDH 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 final disposition of records and radioactive materials;
- The transferee has the financial resources to decommission the license, if necessary; and
- Public health and safety are not compromised by the use of such materials.

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

Notification of Bankruptcy Proceedings

Rule: 12VAC5-481-500

Criteria: 12VAC5-481-500 states: "*Each licensee shall notify the agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against: 1. The licensee 2. An entity (as that term is defined in 11 USC §101 (15)) controlling the licensee or listing the license or licensee as property of the estate; or 3. An affiliate (as that term is defined in 11 USC §101 (2)) of the licensee*" and "*...shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of filing of the petition*".

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

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

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

Item 3: Person to Contact Regarding Application

Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the proposed radiation safety officer, unless the applicant has

named a different person as the contact. VDH will contact this individual if there are questions about the application.

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

Applicants should note that deviations from the suggested responses and submission of alternative procedures may require custom review.

Response from Applicant:

Item 3 Person To Contact Regarding Application:
Contact's Telephone Number (Include Area Code): ( ) - x

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

Specify each proposed location of use by the street address, city, and state or other descriptive address (e.g., on Highway 58, 5 miles east of the intersection of Highway 58 and State Route 16, Anytown, VA). The descriptive address should be sufficient to allow a VDH inspector to find the facility location. **A Post Office box address is not acceptable.** If radioactive material is to be used at more than one location, give the specific address of each location. Applicants for a broad scope license need not identify each facility at a particular address where radioactive material will be used. For example, applicants can specify that radioactive material will be used on the Main Campus of ABC University located in Anytown, VA.

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

If radioactive material (e.g., portable gauging devices) will be used at temporary job sites, specify "*temporary job sites anywhere in the Commonwealth of Virginia where VDH maintains jurisdiction*" and describe the scope of these activities. If radioactive material is to be used in field studies, the activities must be specifically identified and authorized on the license. **Appendix I** contains information required of applicants prior to granting authorization for field use of licensed material.

A VDH-approved license amendment identifying a new location of use, which is not encompassed by a location described on the existing license, is required before receiving, using and storing licensed material at that location.

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

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) ( ) - x
Address , -	Telephone Number (Include Area Code) ( ) - x
Address , -	Telephone Number (Include Area Code) ( ) - x
Is radioactive material used at locations for field studies, other off-site locations or special use facilities? ☐Yes ☐No If yes, please attach an additional sheet(s) with the location address(es) and a list of activities to be conducted at each location.	

Note: As discussed later in **Item 10 'Financial Assurance and Record keeping for Decommissioning,'** licensees need to maintain permanent records on where licensed material was used or stored while the license was in force. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). Acceptable records are sketches, written descriptions of the specific locations, or room numbers where licensed material is used or stored and any records of spills or other unusual occurrences involving the spread of contamination in or around the licensee's facilities.

INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM

Item 5: Executive Management

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

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

Discussion: Executive management is the individual at the senior management level who is responsible for oversight of the radiation safety program and has the ultimate responsibility for the license and the activities associated with the license. Executive management has an important

the license and the activities associated with the license. Executive management has an important role in implementing and managing the radiation safety program. VDH expects executive management to be knowledgeable of the program.

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

In a Type A broad scope program, executive management or her/his delegate is a vital member of the Radiation Safety Committee (RSC) and should attend Committee meetings. In all licensed programs, executive management should be knowledgeable of the results of periodic audits and the annual review of the licensed program, to ensure all activities are in compliance with regulatory requirements and the conditions of the license, and that activities are being conducted in a safe manner. Annual reviews and audits are discussed in more detail in **Item 12, 'Audit Program'**, of this guidance document.

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

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

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

Response from Applicant:

Item 5. **Executive Management** (Check box and provide the information requested)
☐ We will describe and provide administrative controls and provisions relating to organization, management and management review necessary to assure safe operations. We will also provide an organizational chart describing the management structure, reporting paths, and the flow of authority between executive management, the Radiation Safety Committee (for Type A Broad Scope), and the Radiation Safety Officer (for Type A and Type B broad scope).

Item 6: Radiation Safety Committee (RSC)

Rule: 12VAC5-481-470

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

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

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

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

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

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

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

Duties and Responsibilities

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

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

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

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

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

Response from Applicant:

Item 6 Radiation Safety Committee (RSC) (Check all that apply and provide the information requested)

☐ A description of the duties and responsibilities of the RSC is attached.

AND

☐ A description of the criteria used for selecting members of the RSC, including members and the number of members constituting a quorum is attached.

NOTE: Members should be indicated by position title, rather than by name. The chairperson should be identified by name, with training and experience submitted.

AND

☐ A description of the criteria used by the RSC and RSO for approving users and new uses is attached.

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

- A description of the duties and responsibilities of the RSC, including:
  -review and approval of permitted program and procedural changes prior to implementation;
  -implementation of program and procedural changes;
  -audit of licensed operations to determine compliance; and
  -taking appropriate actions when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence.
- A description of the process for procedure and program review and approval, including documentation of the specific change. At a minimum, documentation shall state the reason for the change and summarize the radiation safety matters that were considered prior to approval of the change.

Item 7: Radiation Safety Officer (RSO)

Rule: 12VAC5-481-450 A; 12VAC5-481-470; 12VAC5-481-1310; 12VAC5-481-1750; 12VAC5-481-2680

Criteria: Type A and Type B broad scope licensees must have a Radiation Safety Officer (RSO) who is qualified by training and experience in radiation protection and who is available for advice and assistance on radiological safety matters. The RSO's training and experience must include the types and quantities of licensed material to be authorized on the license. While the

rule does not require Type C broad scope licensees to have an RSO, **12VAC5-481-470** requires that the licensee establish administrative controls and provisions relating to procurement of radioactive material, procedures, recordkeeping, material control and accounting, and management review to assure safe operations. Type C broad scope licensee management should appoint someone responsible for the day-to-day operation of the radiation safety program, such as an RSO.

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

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

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

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

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

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

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

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

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

Response from Applicant:

Item 7 Radiation Safety Officer (RSO) (Check all that apply)

☐ 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.

Name: _____ Telephone Number (Include area code): (_____) _____ - _____ x _____

AND

☐ A delegation of authority letter is included which authorizes the RSO to submit license amendment requests.

AND

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

AND

☐ We will provide a statement delineating the RSO's duties and responsibilities, signed by the licensee's executive management.

FOR TYPE C BROAD SCOPE

☐ We will submit the name of the person who will serve as the individual responsible for the day-to-day operation of the radiation safety program.

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

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

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

Criteria: Before beginning work with or in the vicinity of licensed material, all individuals who are likely to receive an occupational dose in excess of 1 mSv (100 mrem) in a year must receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program. Each individual should also receive periodic refresher training.

Discussion: 12VAC5-481-2270 describes the training that licensees are required to provide individuals who, in the course of their employment, are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). **12VAC5-481-2270** requires that the licensee, in determining which individuals are subject to the training requirements of, consider assigned activities during both normal and abnormal situations involving exposure to radiation and/or radioactive material that can reasonably be expected to occur during the life of a licensed facility. While many licensees can demonstrate that it is not likely during a normal situation for a laboratory worker, manufacturing technician, hospital technologist, or environmental services

worker at their facility to receive in a year an occupational dose in excess of 1 mSv (100 mrem), these individuals and others could reasonably be expected to receive this level of exposure during abnormal situations (e.g., radioactive material left unsecured, a contamination event, or improper disposal of radioactive material in the regular trash) or, by their actions, cause others to receive this level of exposure. Untrained workers represent a potential hazard to themselves, other individuals, and property.

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

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

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

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

Response from Applicant:

Item 8 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.

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

Item 9: Radioactive Material

Unsealed and/or Sealed Radioactive Material

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

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

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

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

A separate listing should also be submitted for sealed sources needed in quantities larger than that described in the atomic number 1-83 request (e.g., self-contained irradiators, instrument calibrators, sealed sources used for medical therapy, portable and non-portable gauging devices, etc.). Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that VDH can verify that they have been evaluated in a Sealed Source and Device (SSD) Registration Certificate or specifically approved on a license. Before the formalization of the SSD registration process, some older sources or devices may have been specifically approved on a license. Licensees can continue to use those sources and devices specifically listed on their licenses. Sealed sources or devices containing sealed sources that are intended for use solely under broad scope licenses and are not transferred to another licensee need not be evaluated by VDH prior to use if: (1) the licensee is authorized to possess the requested quantity of radioactive material in unsealed form; and (2) the licensee performs its own safety evaluation in accordance with the administrative procedures required by **12VAC5-481-470** as appropriate. For example, a broad scope licensee who is authorized to possess and use any form of iridium-192 or cobalt-60 in the fabrication of sources and devices for industrial radiography may use the fabricated sources and devices to conduct its own licensed activities without first submitting the sources and devices to NRC or another Agreement State for evaluation and registration.

If needed, an applicant for a Type A broad scope license may request authorization to possess radioactive materials with atomic numbers greater than 83 (e.g., atomic numbers 84 to 96). For this request, the applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides. Note that

authorization to possess radioactive materials with atomic numbers 84 through 96 does not authorize the possession of uranium, thorium, or plutonium classified as either source material or special nuclear material. Licensees may request authorization for source material and special nuclear material when use of these materials is directly related to the use of radioactive material under the broad scope license (e.g. laboratory-scale research and development or the use of depleted uranium as shielding). Applicants should submit separate applications for the use of source and special nuclear materials for purposes not directly related to the use of radioactive material under the broad scope license (e.g., sub-critical assemblies and nuclear pacemakers).

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

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

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

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

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

- An evaluation showing that the maximum off-site dose due to a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or
- An emergency response plan for responding to the release in accordance with the criteria listed in **12VAC5-481-440 G**.

If you are required to establish an emergency plan, guidance is provided in NRC Regulatory Guide 3.67, "*Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities*", dated January 1992, and NRC Policy and Guidance Directive 84-14, Revision 1, "*Standard Review Plan for Emergency Plans for Fuel Cycle and Materials Licenses*". NRC NUREG 1140, "*A Regulatory Analysis on Emergency Preparedness for Fuel Cycle and Other*

Radioactive Material Licensees, Final Report," dated January 1988, also contains valuable information.

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

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

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

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

Response from Applicant:

Item 9 Radioactive Material (Attach additional pages if necessary)

Atomic Number 1-83 Request

☐ We request authorization for radionuclides with Atomic Number 1-83 in any form with a maximum quantity of _____ per radionuclide and _____ maximum possession limit.

Intended uses include: ☐ non-human research and development activities.
☐ animal studies.
☐ other (list general category of use) _____

Radionuclides in Larger or Smaller Quantities than Atomic Number 1-83 Request - Unsealed sources of radioactive material

Radioisotope				
Chemical/Physical Form				
Maximum Possession Limit				
Proposed use of Radioactive material				

Radionuclides in Larger Quantities than Atomic Number 1-83 Request - Sealed sources of radioactive material

Radioisotope				
Sealed Source Manufacturer or Distributor and Model Number				
Device Manufacturer or Distributor and Model Number				
Maximum Possession Limit				
Proposed Use of Radioactive Material				

Note: If applicable, an evaluation or an emergency response plan is included for radionuclide(s) in excess of the amounts listed in **12VAC5-481-3740**.

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

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

- An evaluation showing that the maximum off-site dose due to a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or
- An emergency response plan for responding to the release in accordance with the criteria listed in **12VAC5-481-470.**

Item 10: Financial Assurance and Recordkeeping for Decommissioning

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

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

- 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 **12VAC5-481-510;**
- Conduct decommissioning, as required by **12VAC5-481-510** and **12VAC5-481-1161**; 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 **12VAC5-481-500**, transfer records important to decommissioning to the new licensee.

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

A licensee authorized to possess licensed material in excess of the limits specified in **12VAC5-481-450 C** must meet the requirements for decommissioning financial assurance. All licensees are required to maintain records of information important to the decommissioning of the facility in an identified location until the site, or any area, is released for unrestricted use. Licensees must transfer these records either to the new licensee, when licensed activities are transferred or assigned, or to VDH when the license is terminated.

Discussion: VDH wants to ensure that decommissioning will be carried out with minimum impact on public and occupational health and safety and the environment. There are two parts to

the rule: financial assurance that applies to some licensees and recordkeeping that applies to all licensees.

VDH decommissioning financial assurance rules are designed to provide reasonable assurance that the decommissioning of licensed facilities will be accomplished in a safe and timely manner and that licensees will provide adequate funds to cover all costs associated with decommissioning. These requirements, if applicable, specify that a licensee either set aside funds for decommissioning activities or provide a guarantee that funds will be available. Applicants are required to provide financial assurance when the possession of radioactive material of half-life (T1/2) greater than 120 days exceeds certain limits. Criteria for determining whether an applicant is required to submit a Decommissioning Funding Plan (DFP) or has an option of submitting either a DFP or a Certification of Financial Assurance are stated in **12VAC5-481-450 C**. A DFP contains a site-specific cost estimate and a certification of financial assurance. A Certification of Financial Assurance includes a certification that the licensee has provided the required financial assurance and an acceptable financial assurance instrument.

Acceptable financial assurance includes prepayment options (trusts, escrow accounts, government funds, certificates of deposit or deposits of government securities); surety, insurance, or other guarantee methods (letters of credit, surety bonds, lines of credit, parent company guarantees, insurance policies), and statements of intent for Government entities. Criteria for parent company guarantees and self-guarantees can be found in **12VAC5-481-450 C**.

NRC Regulatory Guide (RG) 3.66, "*Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72*", dated June 1990, provides guidance acceptable to VDH staff on the information to be provided for establishing financial assurance for decommissioning and a standard format for presenting the information. A revision to RG 3.66 will incorporate new guidance related to self-guarantees. RG 3.66 also describes the information required to be submitted for a DFP. NRC NUREG-1337, Revision 1, "*Standard Review Plan for the Review of Financial Assurance Mechanisms for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72*", dated August 1989, also provides guidance for decommissioning financial assurance reviews.

The requirements for maintaining records important to decommissioning, including the type of information required, are stated in **12VAC5-481-450 C**. All licensees are required to maintain these records in an identified location until the site is released for unrestricted use. Careful recordkeeping of radionuclides used, including form, amount, and area used, will facilitate area release and license termination. In the event that the licensed activities are transferred to another person or entity, these records shall be transferred to the new licensee when the transfer of the licensed activities takes place. The new licensee is responsible for maintaining these records until the license is terminated. When the license is terminated, these records must be transferred to VDH.

Requirements for Disposition of Records Important to Decommissioning

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

OR

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

Response from Applicant:

Item 10 Financial Assurance And Recordkeeping For Decommissioning (Check box)
☐ We will provide a decommissioning funding plan or a certification of financial assurance as required in **12VAC5-481-450 C** (attached if required).

Item 11: Facilities and Equipment

Rule: 12VAC5-481-450 A; 12VAC5-481-470; 12VAC5-481-490; 12VAC5-481-500; 12VAC5-481-630

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

Discussion: Applicants for all broad scope licenses need to demonstrate that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and its employees, keep exposures to radiation and radioactive materials ALARA, and minimize the danger to life and property from the types and quantities of radioactive materials to be used. Facilities and equipment designed to control exposure can range from a vial that contains licensed material, to buildings, fences, or exclusion areas that are between the source and the maximally exposed member of the public. These facilities not only reduce the exposure from the source but may also limit access to the source. The licensee should list and describe these facilities for the following purposes:

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

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

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

guidance on the information that should be addressed concerning the use of radioactive material in animals.

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

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

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

Response from Applicant:

Item 11 Facilities And Equipment (Check all that apply and attach the requested information.)

☐ A description of the criteria used by the RSC (Type A) or RSO (Type B), as appropriate, that will be used to review and approve facilities and equipment (research laboratories, iodination facilities, waste storage facilities, survey and counting equipment, etc.) is attached.

NOTE: See Appendices K and L of VAREG 'Guidance for Licenses of Broad Scope' for guidance.

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

Item 12 Radiation Safety Program

Item 12.1: Audit Program

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

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

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

Discussion:

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

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

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

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

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

- Review of user inventory and survey records
- Evaluation of user and technician training through discussion and observation of work practices
- Performance of independent surveys of user work areas

- Evaluation of compliance with **12VAC5-481 'Virginia Radiation Protection Regulations'**, the conditions of the license, the RSC/RSO permit and safety manual requirements
- Provision for performance-based instruction to users and technical-level staff.

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

If an audit identifies violations of **12VAC5-481 'Virginia Radiation Protection Regulations'**, the licensee should evaluate the safety significance of each violation to set priorities and identify resources to correct these violations. NRC Information Notice (IN) 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996, provides guidance on this subject. Certain identified problems or potential violations may require notification or a report to the VDH. **Appendix N** of this document describes the more common VDH reporting requirements. Licensees are encouraged to contact VDH for guidance if there is any uncertainty regarding a reporting requirement. VDH routinely reviews licensees' records to verify if appropriate corrective actions were implemented in a timely manner to prevent recurrence. It is in the best interest of the licensee to identify potential violations of regulatory requirements and take necessary steps to correct them. VDH can exercise discretion and may elect not to cite the licensee for these violations if prompt and effective corrective actions are implemented.

VDH's emphasis in inspections is for applicants 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, safe use of radionuclide procedures and emergency procedures are available and are being followed.

Recordkeeping

12VAC5-481-990 requires that licensees maintain records of audits and other reviews of program content and implementation for 3 years from the date of the record. Records of audits should include: date of audit, name of person(s) who conducted the audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up. These records must be maintained for inspection by VDH.

Response From Applicant:

Item 12.1 Audit Program (Check all that apply)

☐ A description of the mechanisms used by executive management to ensure that adequate oversight of the Broad Scope Radiation Safety program is exercised, is attached.

AND

☐ A description of the audit mechanism implemented by the RSO to determine user compliance with **12VAC5-481 'Virginia Radiation Protection Regulations'**, the terms and conditions of the VDH license, the requirements of the RSC (Type A) or RSO-approved permits (Type B) as appropriate, and good health physics practices are attached.

NOTE: 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.

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

Item 12.2: Radiation Monitoring Instruments

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

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

Discussion: Licensees must possess an adequate number of radiation detection and measurement instruments as necessary and ensure they are calibrated periodically for the radiation being measured. For purposes of this document, survey instruments are defined as any device used to measure the radiological conditions at a licensed facility. The choice of instrument needs to be appropriate for the type of radiation to be measured and for the type of measurement to be taken (count rate, dose rate, etc.).

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

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

this document provides useful information about instrument specifications and sample calibration procedures that are acceptable to VDH.

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

Response from Applicant:

Item 12.2 Radiation Monitoring Instruments (Check all that apply)

☐ A description of the criteria used by the RSC (Type A) or RSO (Type B), as appropriate, to review and approve radiation monitoring instrumentation to assure that appropriate radiation monitoring equipment will be used during licensed activities is attached.

AND

☐ A description of how the RSC (Type A) or RSO (Type B), as appropriate, will assure that instruments are properly calibrated at prescribed frequencies is attached.

AND ONE OF THE FOLLOWING

☐ Instruments will be calibrated by an organization licensed by VDH, the NRC or another Agreement State to perform instrument calibrations.

OR

☐ We will follow the procedures for instrument calibrations in Appendix O of VAREG 'Guidance for Licenses of Broad Scope'.

OR

☐ A description of alternative procedures is provided for ensuring that proper calibration of survey equipment will be performed. (Procedures are attached)

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

If you wish to perform instrument calibration as a commercial service, you will need to either amend your existing broad scope license or apply for a new VDH license authorizing commercial calibration service.

Item 12.3: Material Receipt and Accountability

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

Criteria: Licensees must, pursuant to **12VAC5-481 'Virginia Radiation Protection Regulations', Parts I and IV**, develop, implement, and maintain written procedures for all of the following:

- Purchasing and receipt of radioactive material

- Safely receiving and opening packages
- Ensuring control and accountability of licensed material.

The licensee must also maintain records of receipt, utilization, transfer, and disposal of licensed material.

Discussion: Applicants for a broad scope license are required to establish appropriate administrative controls and provisions that are necessary to assure safe operations including procedures to assure the control of procurement and use of radioactive material. Administrative procedures must assure that only authorized individuals receive radioactive materials and that individuals receive only the types and quantities of radioactive material that they are authorized to receive.

Applicants for a broad scope license are strongly encouraged to develop an administrative procedure to control procurement and use of radioactive material that emphasizes centralized purchasing and receipt. VDH has found centralized purchasing and receipt to be effective in controlling licensed materials entering the licensed institution through normal commercial channels, particularly for larger institutions. Procedures must also be established to control licensed materials obtained outside of the normal channels (e.g., through the loan or transfer of materials without purchase or through surplus). **Appendix P** of this document describes a sample procedure for controlling procurement and use of radioactive material that is acceptable to VDH.

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

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

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

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

Licensees must maintain records of receipt, use, transfer, and disposal of all licensed material. **Table 2** below lists each type of record and how long the record must be maintained.

Table 2: Record Maintenance

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

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

Response from Applicant:

Item 12.3 Material Receipt And Accountability (Check all boxes)

☐ A description of administrative procedures to assure control of procurement and use of radioactive material is attached.

AND

☐ A description of administrative controls and provisions relating to material control, accounting, and security is attached.

AND

☐ We will develop, implement, and maintain procedures for safe opening of packages containing radioactive material.

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

Item 12.4: Occupational Dosimetry

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

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

- Adults who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
  - 0.005 Sv (0.5 rem) deep-dose equivalent.
  - 0.015 Sv (1.5 rems) eye dose equivalent.
  - 0.05 Sv (5 rems) shallow-dose equivalent to the skin.
  - 0.05 Sv (5 rems) shallow-dose equivalent to any extremity.
- Minors who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
  - 1.0 mSv (0.1 rem) deep-dose equivalent.
  - 1.5 mSv (0.15 rem) eye dose equivalent.
  - 0.005 Sv (0.5 rem) shallow-dose equivalent to the skin.
  - 0.005 Sv (0.5 rem) shallow-dose equivalent to any extremity.
- Declared pregnant women who are likely to receive an annual dose from occupational exposures in excess of 1.0 mSv (0.1 rem) deep-dose equivalent, although the dose limit applies to the entire gestation period.
- Individuals entering a high or very high radiation area.

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

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

Discussion: If an adult is likely to receive in 1 year a dose greater than 10% of any applicable limit (see **Table 3**), monitoring is required. The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose. This evaluation need not be made for every individual. Evaluations can be made for employees with similar job functions or work areas.

Table 3: Occupational Dose Limits for Adults

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

If this prospective evaluation shows that the individual is not likely to exceed 10% of any applicable limit, there are no recordkeeping or reporting requirements in regard to the individual's exposure. For individuals who received exposure at other facilities in the current year, the previous dose need not be considered in this prospective evaluation. Only dose that could be received at the facility performing the evaluation need be considered when determining the need for monitoring, and therefore, recordkeeping and reporting requirements. If it is determined that monitoring is not required and a subsequent evaluation shows that the 10% threshold has or will be exceeded, the dose received when monitoring was not provided should

be estimated, recorded, and reported. These estimates can be based on any combination of work location radiation monitoring or survey results, monitoring results of individuals in similar work situations or other estimates to produce a 'best estimate' of the actual dose received.

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

If the prospective evaluation shows that the individual is likely to exceed 10% of an applicable limit, then monitoring and reporting of the results of monitoring performed, regardless of the actual dose received, is required. If air sampling or bioassay is required, discussion of air sampling or bioassay should provide enough detail that the VDH staff is assured that appropriate steps will be taken to manage and monitor such exposure.

Table 4: Nuclear Regulatory Commission Documents that Contain Guidance Relating to Personnel Monitoring and Bioassay that may be Applicable

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

Additional References for Further Reading:

1. U.S. Department of Energy DOE G 441.1-2, "*Occupational ALARA Program Guide*", March 17, 1999.
2. U.S. Department of Energy DOE G 441.1-3, "*Internal Dosimetry Program Guide*", March 17, 1999.

3. U.S. Department of Energy DOE G 441.1-4, "*External Dosimetry Program Guide*", March 17, 1999.
4. U.S. Department of Energy DOE G 441.1-8, "*Air Monitoring Guide*", March 17, 1999.
5. U.S. Department of Energy DOE G 441.6-1, "*Evaluation and Control of Radiation Dose to the Embryo/Fetus*", April 1998.

Response from Applicant:

Item 12.4 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 **12VAC5-481-640**.

AND / OR

☐ We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged at a frequency recommended by the processor.

Item 12.5: Public Dose

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

Criteria: Licensees must ensure that licensed material will be used, transported, stored, and disposed in such a way that the total effective dose equivalent (TEDE) to members of the public will not exceed 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.

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

There are both external exposure components and internal exposure components of public dose. The licensee should review all possible internal and external exposure pathways and decide which are applicable to its operations.

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

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

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

Response from Applicant:

Item 12.5 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 12.6: Safe Use of Radionuclides and Emergency Procedures

Rule: 12VAC5-481-440; 12VAC5-481-450; 12VAC5-481-470; 12VAC5-481-500; 12VAC5-481-630; 12VAC5-481-720; 12VAC5-481-840; 12VAC5-481-860; 12VAC5-481-870; 12VAC5-481-880; 12VAC5-481-890; 12VAC5-481-1090; 12VAC5-481-1100; 12VAC5-481-1110; 12VAC5-481-2260; 12VAC5-481-3740; 12VAC5-481-3760

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

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

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

All licensed materials that are stored in controlled or unrestricted areas must be secured from unauthorized access or removal, so that individuals who may not be knowledgeable about radioactive materials cannot be exposed to or contaminated by the material, and individuals cannot take the material. When any licensed materials are in use in controlled or unrestricted areas, they must be under constant surveillance so that the radiation worker can prevent others from becoming contaminated by or exposed to the material or prevent persons from removing the material from the area.

Acceptable methods for securing material will vary from one facility to another. Some alternatives used by licensees include:

- Storage and use of licensed materials only in restricted areas;
- Limiting access to an entire facility or building or portion of the building only to radiation workers;
- Providing storage areas that can be locked to prevent access to the material; and

- Implementing procedures that require a radiation worker to be within 'line of sight' of the materials whenever licensed materials are in use.

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

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

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

Applicants need to establish written procedures to handle emergencies ranging from a minor spill to a major accident that may require intervention by outside emergency response personnel. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of users and the radiation safety staff. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, individual users should have a clear understanding of their limitations in an emergency, with step-by-step instructions and clear direction of whom to contact. Emergency Procedures that are acceptable to VDH are described in **Appendix R** of this document.

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

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

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

Response from Applicant:

Item 12.6 Safe Use Of Radionuclides And Emergency Procedures (Check one box)
☐ We will develop, implement, and maintain procedures for the safe use of radionuclides and emergencies that will meet the criteria in the section titled 'Safe Use of Radionuclides and Emergency Procedures' in VAREG 'Guidance for Licenses of Broad Scope'. (Procedures are attached)
OR
☐ We will follow procedures for the safe use of radionuclides and emergencies in Appendix R of VAREG 'Guidance for Licenses of Broad Scope'.

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

Item 12.7: Leak Tests

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

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

Discussion: A leak test will be required for sealed/plated foil sources at six month intervals, as approved by VDH in a license condition or by the NRC or another Agreement State as specified by the Sealed Source and Device (SSD) Registration Certificate. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 becquerels (Bq) (0.005 microcuries) of radioactivity.

Leak tests are not required if:

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

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

Response from Applicant:

Item 12.7 Leak Tests (Check one box)

☐ 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 supplier's instructions.

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

Organization Name_____ License Number _____
Issuing Agency _____

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 another Agreement State.

OR

☐ We will perform leak testing and sample analysis and will follow the model procedures in Appendix T of VAREG 'Guidance for Licenses of Broad Scope'. (Procedures are attached)

OR

☐ We will submit alternative procedures. (Procedures are attached)

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

Item 12.8: Surveys

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

Criteria: Licensees are required, pursuant to the requirements listed above, to make surveys of potential radiological hazards in their workplace. Records of surveys must be maintained.

Discussion: A survey is defined in **12VAC5-481-10** as, "*an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a, physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.*." These evaluations may be measurements (e.g., radiation levels measured with a survey instrument or results of wipe tests for contamination), calculation, or a combination of measurements and calculations. The licensees must interpret and evaluate such measurements and calculations to take appropriate action. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess the radiological conditions. Surveys are also used to plan work in areas where radioactive material is present and to evaluate doses to workers and individual members of the public. In certain cases, environmental monitoring may be required to demonstrate compliance with **12VAC5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation'.**

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

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

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect the worker from external and internal exposure. Also, the frequency of the survey depends on the type of survey, such as those listed above.

12VAC5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation' does not specify limits for surface contamination. Each applicant should propose and justify what removable surface contamination limits will be allowable before decontamination will be performed in each work area.

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

NRC NUREG/BR-0241, "*NMSS Handbook for Decommissioning Fuel Cycle and Materials Licenses*", dated March 1997, contains the current regulatory guidance concerning decommissioning of facilities and termination of licenses. Appendix B of the handbook contains a comprehensive list of NRC's decommissioning regulations and guidance. In addition, NUREG-1575, "*Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)*", dated December 1997, should be reviewed by licensees who have large facilities to decommission.

Response from Applicant:

Item 12.8 Surveys (Check one box)

☐ We will develop, implement and maintain procedures for area surveys that will meet the criteria in the section titled 'Surveys' in VAREG 'Guidance for Licenses of Broad Scope'. (Procedures are attached)

OR

☐ We will follow the procedures for area surveys in Appendix S of VAREG 'Guidance for Licenses of Broad Scope'.

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

Item 12.9: Termination of Activities

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

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

- Notify VDH, in writing, within 60 days of:
  - the expiration of its license
  - a decision to permanently cease licensed activities at the entire site (regardless of contamination levels)
  - a decision to permanently cease licensed activities in any separate building or outdoor area, if they contain residual radioactivity making them unsuitable for release according to NRC requirements
  - no principal activities having been conducted at the entire site under the license for a period of 24 months
  - no principal activities having not been conducted for a period of 24 months in any separate building or outdoor area, if they contain residual radioactivity making them unsuitable for release according to VDH requirements.
- Submit decommissioning plan, if required by **12VAC5-481-510**.
- Conduct decommissioning, as required by **12VAC5-481-510** and **12VAC5-481-1161**.
- Submit, to VDH, a completed VDH Form, 'Certificate of Disposition of Materials' (**Appendix B**) and a demonstration that the premises are suitable for release for unrestricted use (e.g., results of final survey).
- Before a license is terminated, send all records pertaining to decommissioning to VDH. If licensed activities are transferred or assigned in accordance with **12VAC5-481-500**, transfer records important to decommissioning to the new licensee.

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

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

NRC Draft Regulatory Guide DG-4006, "*Demonstrating Radiological Criteria For License Termination*", issued July 8, 1998 and NUREG/BR-0241, "*NMSS Handbook for Decommissioning Fuel Cycle and Materials Licenses*", dated March 1997, contains the current regulatory guidance concerning decommissioning of facilities and termination of licenses. Appendix B of the Handbook contains a comprehensive list of NRC's decommissioning regulations and guidance. NUREG-1575, "*Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)*", dated December 1997, should be reviewed by licensees who have large facilities to decommission. An acceptable screening computer code for calculating screening values to demonstrate compliance with the unrestricted dose limits is D and D, Version 1; this was issued on August 20, 1998. Supplemental information on the implementation of the final rule on radiological criteria for license termination was published in the Federal Register (Volume 63, Number 222, Page 64132-64134) on November 18, 1998. This includes the

following acceptable license termination screening values of common radionuclides for building surface contamination.

Table 5: Acceptable License Termination Screening Values of Common Radionuclides for Building Surface Contamination

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

* Screening levels are based on the assumption that the fraction of removable surface contamination is equal to 0.1. For cases when the fraction of removable contamination is undetermined or higher than 0.1, users may assume, for screening purposes, that 100% of surface contamination is removable; and therefore the screening levels should be decreased by a factor of 10. Alternatively, users having site-specific data on the fraction of removable contamination (e.g., within 10% to 100% range) may calculate site-specific screening levels using D and D Version 1, based on site-specific re-suspension factor. For Unrestricted Release (dpm/100 cm^2) units are disintegrations per minute per 100 square centimeters (dpm/100 cm^2). 1 dpm is equivalent to 0.0167 becquerel (Bq). The screening values represent surface concentrations of individual radionuclides that may be deemed in compliance with the 0.25 mSv/yr (25 mrem/yr) unrestricted release dose limit in **12VAC5-481-1161**. For radionuclides in a mixture, the 'sum of fractions' rule applies; see **12VAC5-481-3750**.

Response from Applicant:

Item 12.9 Termination Of Activities

☐ We will notify the agency, in writing, within 60 days of the decision to permanently cease radioactive material use per **12VAC5-481-510 D**.

Item 12.10: Transportation

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

Criteria: Broad Scope licensees 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: DOT regulations (**49 CFR**) were written to help assure that transportation of hazardous materials in commerce is transported uniformly and safely. VDH licensees who transport radioactive material (hazardous material) in commerce would, therefore, be required to comply with all applicable regulations found in DOT. However, many VDH licensees routinely transport radioactive material that is not in commerce. **Appendix U** of this document provides an overview of the transportation requirements commonly affecting VDH licensees. Licensees may also wish to review NUREG-1660, "*U.S.-Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments*", published jointly by NRC and DOT in November 1998.

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

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

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

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

Response from Applicant:

Item 12.10 Transportation
No response is needed from applicant during the licensing process; this issue will be reviewed during inspection.

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

Item 13: Waste Management

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

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

Discussion: The applicant should discuss the methods for management and disposal of radioactive waste. The program should include procedures for handling of waste, safe and secure storage, waste characterization, waste minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. Licensees may not receive radioactive waste from other licensees for processing, storage, or disposal unless specifically authorized.

The U.S. Environmental Protection Agency (EPA) issued guidance for developing a comprehensive program to reduce hazardous waste. This guidance was transmitted to NRC licensees by the NRC in IN-94-23, "*Guidance to Hazardous, Radioactive, and Mixed Waste Minimization Program*", dated March 1994. The application should include, where appropriate for the types of waste involved, provisions for monitoring and segregating waste materials (radioactive from non-radioactive, short from long half-life, liquid from solid waste, etc.).

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

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

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

to workers, members of the public, and the environment. Safety procedures to address these concerns should be implemented.

Decay-In-Storage (DIS) and Extended Interim Storage
VDH has concluded that materials with half-lives of less then or equal to 120 days are appropriate for DIS and interim storage. The minimum holding period for decay is ten half-lives of the longest lived radioisotope in the waste. Such waste may be disposed of as ordinary trash if radiation surveys (performed in a low background area and without any interposed shielding) of the waste at the end of the holding period indicate that radiation levels are indistinguishable from background. All radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash. If the decayed waste is compacted, all labels that are visible in the compacted mass must also be defaced or removed.

VDH does not consider storage as a substitute for final disposal of radioactive wastes. Other than storage for radioactive decay, LLW should be stored only when disposal capacity is unavailable and for no longer than is necessary. NRC Information Notice No. 90-09, "*Extended Interim Storage of Low-Level Radioactive Waste for Fuel Cycle and Material Licensees*", dated February 1990, provides guidance to licensees for requesting an amendment to authorize extended interim storage of LLW.

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

Release into Air and Water
Release of radioactive material into air and water must conform to the requirements described in **12VAC5-481-730**. The applicant should discuss the monitoring and control mechanisms in place to ensure compliance with the requirements. Applicants are reminded of the 'constraint' on air emissions of radioactive material required by **12VAC5-481-630**, which effectively reduces the limits specified in **12VAC5-481-730** for release of gaseous effluents. Applicants, who are considering release of radioactive material into air and water should review NRC Regulatory Guide 8.37, "*ALARA Levels for Effluents From Materials Facilities*", dated July 1993. Regulatory Guide 8.37 deals with the application of ALARA in controlling gaseous and liquid effluents, and references documents containing acceptable methods of effluent monitoring.

Licensees considering disposal by release to the sanitary sewerage system must comply with the requirements of **12VAC5-481-930**. **12VAC5-481-930** authorizes disposal of licensed material by release into a public sanitary sewerage system if certain conditions are met. Licensees are responsible for demonstrating that licensed materials discharged into the public sewerage system are readily soluble in water or are biological materials that are readily dispersible in water. NRC Information Notice, No. 94-07, "*Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20*", dated January 1994, provides the criteria for evaluating solubility of waste. Licensees should carefully consider the possibility of re-concentration of radioisotopes that are released into the sewer. The NRC alerted licensees to the potentially significant problem of re-concentration of radionuclides released to sanitary sewerage systems in NRC's Information Notice No. 84-94, "*Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems Permitted Under 10 CFR 20.203* (now 10 CFR 20.2003)", dated December 1984.

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

If your facility maintains a private sewerage treatment system, a septic system, or leach fields, the requirements of **12VAC5-481-930** are not applicable for releases to these systems (see **12VAC5-481-10**, definition of "S*anitary Sewerage*"). You may make releases of liquids to private sewerage systems, septic systems, or leach fields as effluents released to unrestricted areas pursuant to **12VAC5-481-730.**

If liquid releases are made to a private sewerage treatment system, septic system, or leach field, the sludges or other solids from these systems may become contaminated with radioactive material. Applicants should describe the monitoring planned for these systems. Contaminated sludges will be required to be disposed of as radioactive waste using one of the methods described in this section. Applicants may obtain approval of alternative disposal methods through application to VDH, as described in **12VAC5-481-920**.

Incineration

Applicants who wish to treat or dispose of licensed material by incineration must comply with the requirements of **12VAC5-481-940**. Applicants proposing incineration should be aware that notification and approval by the Virginia Department Environmental Quality (VDEQ) is required before ash may be disposed of as ordinary waste in the Commonwealth of Virginia. However, approval of incineration pursuant to **12VAC5-481-940** does not require notification and approval by the VDEQ if the ash is disposed as radioactive waste or transferred to a specific licensee. Nuclear Regulatory Commission (NRC) Policy and Guidance Directive PG 8-10, "*Disposal of Incinerator Ash as Ordinary Waste*", dated January 1997, provides guidance relative to the disposal of ash. A sample procedure for incineration of waste is described in **Appendix V** of this guidance document.

Applicants who are considering disposal of radioactive material by incineration should review NRC Regulatory Guide 8.37, "*ALARA Levels for Effluents From Materials Facilities*", dated July 1993. Regulatory Guide 8.37 deals with the application of ALARA in controlling gaseous and liquid effluents and references documents containing acceptable methods of effluent monitoring.

Waste Volume Reduction

Waste volume reduction operations that could create a radiological hazard to licensee employees or the general public must be described in detail in the application. A sample procedure for waste compaction is described in **Appendix V** of this guidance document.

Disposal of Specific Waste As If It Were Not Radioactive

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

- Liquid scintillation medium containing no more than 1.85 kBq (0.05 microcuries) of hydrogen-3, iodine-125, or carbon-14 per gram of the medium; and

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

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

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

Other Methods Specifically Approved by VDH Pursuant to 12VAC5-481-920
Applicants may also request alternate methods for the disposal of radioactive waste generated at their facilities. Such requests must describe the waste containing licensed material, including the physical and chemical properties that may be important to assess risks associated with the waste and the proposed manner and conditions of waste disposal. Additionally, the applicant must submit its analysis and evaluation of pertinent information on the nature of the environment, nature and location of other affected facilities, and procedures to ensure that radiation doses are maintained ALARA and within regulatory limits.

The application should describe the ALARA considerations taken before disposal of radioactive materials. Discuss the potential for unmonitored or unanticipated release of radioactive materials to work areas and from release points (i.e., hoods and incinerator stacks). To be in compliance with the ALARA philosophy stated in **12VAC5-481-630**, radioactive material waste stream concentrations should be a fraction (generally 10% to 20%) of the limits specified in **12VAC5-481-3690.** Furthermore, due to the variability of inventory control programs for monitoring disposal and releases of radioactive material in use, a program for physically measuring releases should be in place whenever releases exceed the specified ALARA action point.

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

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

Response from Applicant:

Item 13 Waste Management (Check box)
☐ We will develop, implement and maintain procedures for waste collection, storage, and the disposal of radioactive material, that will meet the criteria in the section titled 'Waste Management' in VAREG 'Guidance for Licenses of Broad Scope'. (Procedures are attached) **Note**: Appendix V in VAREG 'Guidance for Licenses of Broad Scope' provides sample procedures for waste management.

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

The next two items on VDH Form 'Application for Radioactive Material for Broad Scope' are to be completed on the form itself.

Item 14: License Fees

On VDH Form, 'Application for Radioactive Material for Broad Scope' enter the appropriate fee category from **12VAC5-490** and the amount of the fee enclosed with the application.

Response from Applicant:

Item 14 License Fees (Refer to **12VAC5-490**.)	
Category:	License fee enclosed: ☐ Yes ☐ No Amount Enclosed _____

Item 15: Certification

Representatives of the corporation or legal entity filing the application should date and sign VDH Form, 'Application for Radioactive Material for Broad Scope'. Representatives signing an application must be authorized to make binding commitments and to 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. VDH will return all unsigned applications for proper signature.

Note:

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

Response from Applicant:

Item 15	
I hereby certify that this application was prepared in conformance with the **12VAC5-481 '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 A:

VDH Form, 'Application for Radioactive Material License for Broad Scope'

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

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE FOR BROAD 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 Licenses of Broad Scope'. Use supplementary sheets where necessary. Retain one copy and submit original of the entire application to the Virginia Department of Health, Radioactive Materials Program, 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): ( ) - x	Contact's Telephone Number (Include Area Code): ( ) - x

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

Is radioactive material used at locations for field studies, other off-site locations or special use facilities? ☐ Yes ☐ No

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

INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM

Item 5 Executive Management (Check box and provide the information requested)

☐ We will describe and provide administrative controls and provisions relating to organization, management and management review necessary to assure safe operations. We will also provide an organizational chart describing the management structure, reporting paths, and the flow of authority between executive management, the Radiation Safety Committee (for Type A Broad Scope), and the Radiation Safety Officer (for Type A and Type B Broad Scope).

Item 6 Radiation Safety Committee (RSC) (Check all that apply and provide the information requested)

☐ A description of the duties and responsibilities of the RSC is attached.

AND

☐ A description of the criteria used for selecting members of the RSC, including members and the number of members constituting a quorum is attached.

NOTE: Members should be indicated by position title, rather than by name. The chairperson should be identified by name, with training and experience submitted.

AND

☐ A description of the criteria used by the RSC and RSO for approving users and new uses is attached.

Item 7 Radiation Safety Officer (RSO) (Check all that apply)

☐ 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.

Name: _____ Telephone Number (Include area code): (___) ___ - ___ x _____

AND

☐ A delegation of authority letter is included which authorizes the RSO to submit license amendment requests.

AND

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

AND

☐ We will provide a statement delineating the RSO's duties and responsibilities, signed by the licensee's executive management.

FOR TYPE C BROAD SCOPE

☐ We will submit the name of the person who will serve as the individual responsible for the day-to-day operation of the radiation safety program.

TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Item 8 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 9 Radioactive Material (Attach additional pages if necessary)

Atomic Number 1-83 Request

☐ We request authorization for radionuclides with Atomic Number 1-83 in any form with a maximum quantity of _____ per radionuclide and _____ maximum possession limit.

Intended uses include: ☐ non-human research and development activities.
☐ animal studies.
☐ other (list general category of use)

Radionuclides in Larger or Smaller Quantities than Atomic Number 1-83 Request - Unsealed sources of radioactive material

Radioisotope				
Chemical/Physical Form				
Maximum Possession Limit				
Proposed use of Radioactive material				

Radionuclides in Larger Quantities than Atomic Number 1-83 Request - Sealed sources of radioactive material

Radioisotope				
Sealed Source Manufacturer or Distributor and Model Number				
Device Manufacturer or Distributor and Model Number				
Maximum Possession Limit				
Proposed Use of Radioactive Material				

Note: If applicable, an evaluation or an emergency response plan is included for radionuclide(s) in excess of the amounts listed in **12VAC5-481-3740.**

FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING

Item 10 Financial Assurance And Recordkeeping For Decommissioning (Check box)

☐ We will provide a decommissioning funding plan or a certification of financial assurance as required in **12VAC5-481-450 C.** (Attached if required)

FACILITIES AND EQUIPMENT

Item 11 Facilities And Equipment (Check all that apply and attach the requested information)

☐ A description of the criteria used by the RSC (Type A) or RSO (Type B), as appropriate, that will be used to review and approve facilities and equipment (research laboratories, iodination facilities, waste storage facilities, survey and counting equipment, etc.) is attached.

NOTE: See Appendices K and L of VAREG 'Guidance for Licenses of Broad Scope' for guidance.

Item 12 Radiation Safety Program

Item 12.1 Audit Program (Check all that apply)

☐ A description of the mechanisms used by executive management to ensure that adequate oversight of the Broad Scope Radiation Safety program is exercised, is attached.

AND

☐ A description of the audit mechanism implemented by the RSO to determine user compliance with **12VAC5-481 'Virginia Radiation Protection Regulations'**, the terms and conditions of the VDH license, the requirements of the RSC (Type A) or RSO-approved permits (Type B) as appropriate, and good health physics practices are attached.

NOTE: 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 12.2 Radiation Monitoring Instruments (Check all that apply)

☐ A description of the criteria used by the RSC (Type A) or RSO (Type B), as appropriate, to review and approve radiation monitoring instrumentation to assure that appropriate radiation monitoring equipment will be used during licensed activities is attached.

AND

☐ A description of how the RSC (Type A) or RSO (Type B), as appropriate, will assure that instruments are properly calibrated at prescribed frequencies is attached.

AND ONE OF THE FOLLOWING

☐ Instruments will be calibrated by an organization licensed by VDH, the NRC or another Agreement State to perform instrument calibrations.

OR

☐ We will follow the procedures for instrument calibrations in Appendix O of VAREG 'Guidance for Licenses of Broad Scope'.

OR

☐ A description of alternative procedures is provided for ensuring that proper calibration of survey equipment will be performed. (Procedures are attached)

Item 12.3 Material Receipt And Accountability (Check all boxes)

☐ A description of administrative procedures to assure control of procurement and use of radioactive material is attached.

AND

☐ A description of administrative controls and provisions relating to material control, accounting and security is attached.

AND

☐ We will develop, implement, and maintain procedures for safe opening of packages containing radioactive material.

Item 12.4 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 **12VAC5-481-640**.

OR

☐ We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged at a frequency recommended by the processor.

Item 12.5 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 12.6 Safe Use Of Radionuclides And Emergency Procedures (Check one box)

☐ We will develop, implement and maintain procedures for the safe use of radionuclides and emergencies that will meet the criteria in the section titled 'Safe Use of Radionuclides and Emergency Procedures' in VAREG 'Guidance for Licenses of Broad Scope'. (Procedures are attached)

OR

☐ We will follow procedures for the safe use of radionuclides and emergencies in Appendix R of VAREG 'Guidance for Licenses of Broad Scope'.

Item 12.7 Leak Tests (Check one box)

☐ 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 supplier's instructions.

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

Organization Name: _____ License Number: _____

Issuing Agency: _____

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

OR

☐ We will perform leak testing and sample analysis and will follow the model procedures in Appendix T of VAREG 'Guidance for Licenses of Broad Scope'. (Procedures are attached)

OR

☐ We will submit alternative procedures. (Procedures are attached)

Item 12.8 Surveys (Check one box)

☐ We will develop, implement and maintain procedures for area surveys that will meet the criteria in the section titled 'Surveys' in VAREG 'Guidance for Licenses of Broad Scope'. (Procedures are attached)

OR

☐ We will follow the procedures for area surveys in Appendix S of VAREG 'Guidance for Licenses of Broad Scope'.

Item 12.9 Termination Of Activities

☐ We will notify the agency, in writing, within 60 days of the decision to permanently cease radioactive material use per **12VAC5-481-510 D**.

Item 12.10 Transportation

No response is needed from applicant during the licensing process; this issue will be reviewed during inspection.

Item 13 Waste Management (Check box)

☐ We will develop, implement and maintain procedures for waste collection, storage, and the disposal of radioactive material, that will meet the criteria in the section titled 'Waste Management' in VAREG 'Guidance for Licenses of Broad Scope'. (Procedures are attached)

Note: Appendix V in VAREG 'Guidance for Licenses of Broad Scope' provides sample procedures for waste management.

SPECIFIC LICENSE FEE

Item 14 License Fees (12VAC5-490.)

Category:	License fee enclosed: ☐ Yes ☐ No Amount Enclosed: _____

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

Item 15

I hereby certify that this application was prepared in conformance with the **12VAC5-481 '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 Materials'

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

CERTIFICATE OF DISPOSITION OF MATERIALS

Completion of this form is required to complete termination of a Radioactive Material License as outlined in **12VAC5-481-510**. Failure to provide information will result in this request for termination of a specific license not being processed.

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

CONTACT INFORMATION

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

TERMINATION AND DISPOSITION INFORMATION

The following information is provided in accordance with **12 VAC 5-481-510.** (Check all that apply)

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

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

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

☐ Transferred to: Name Address

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

Issued by (Licensing Agency):

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

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

☐ Other (Attach additional pages)

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

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

Name:

Address:

Contact Person Telephone Number: ( ) - x

Additional remarks (Attach additional pages if necessary.)

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

Item 10.

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

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

Print Name and Title of above signatory

Appendix C:

RESERVED

Appendix D:

RESERVED

Appendix E:

RESERVED

Appendix F:

RESERVED

Appendix G:

RESERVED

Appendix H:

Information Needed for Transfer of Control Application

Information Needed for Transfer of Control Application

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

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

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

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

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

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

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

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

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

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

Appendix I:

Information Needed for Field Use of Radioactive Material

Information Needed for Field Use of Radioactive Material

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

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

Appendix J:

Sample Delegation of Authority for the Radiation Safety Officer

Memorandum To: All Employees

From: Chief Executive Officer

Subject: Delegation of Authority for Radiation Safety Officer

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

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

_____ _____

Signature Date

_____

Title

Appendix K:

Radionuclides Classified According to Relative Toxicity

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

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

Table 6: Radionuclides Classified According to Relative Radiotoxicity (Excerpted from IAEA Safety Standard, Safety Series No. 1, "*Safe Handling of Radionuclides, 1973 Edition*")

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

Table 7: Limitations on Activities in Various Types of Working Place or Laboratory

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

Appendix L:

Facilities and Equipment Considerations

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

- Restricted areas are defined as areas to which access is limited by the licensee to protect individuals against undue risks from exposure to radiation and radioactive materials. The application should contain detailed descriptions and diagrams of the facilities, including information about the shielding properties of the construction materials used. Scaled drawings and sketches should be submitted showing the relationship between restricted areas and unrestricted areas and the location of all pertinent safety-related equipment.

- Bench top or open work areas may be used for sealed sources, for small quantities of solid materials in a form not likely to become airborne or dispersed, and for small quantities of liquids of such low volatility as not to cause airborne contamination or toxicity problems. Trays and/or absorbent surface covers to catch and retain spilled liquids should be used on these open work surfaces and inside closed systems discussed below. Surfaces should be smooth and non-porous to facilitate decontamination.

- Radioactive materials that are handled or used in unsealed forms should be confined to control the release of material and to prevent the spread of contamination. Gaseous, volatile, and fine particulate solid materials should be handled in closed or isolated systems such as fume hoods or glove boxes with controlled, and possibly filtered, exhaust systems.

  Chemical-type fume hoods provide a working area with controlled inward airflow from the room to the hood exhaust system. Hoods are used for gases, for unsealed volatile licensed materials, and for processes such as evaporation, that may release gases and vapors. Fume hoods provide emergency ventilation and exhaust for unplanned releases, such as accidental spills and ruptures, as well as routine exhaust of effluents. Filters may be required in the exhaust stream unless monitoring and/or calculations demonstrate that any planned or likely effluent will be in accordance with the limits found in **12VAC5-481-3690**.

  Glove boxes are sealed boxes with transparent viewing windows, sealable ports or doors for transferring materials and equipment, and gloves sealed to the box through which licensed materials are handled. Glove boxes are used for the containment during storage and use of liquids and solids that can become airborne particulates or aerosols. Glove boxes can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.

- Sink faucets should be designed, where possible, for operation by foot, knee, or elbow rather than by hand.

- Plumbing and ductwork should be designed to avoid radioactive contamination build-up. This build-up of contamination can create external radiation exposure hazards and problems for decommissioning.

- Shielding consisting of lead or other high-density material in the form of bricks, panels, L-shields, storage containers, or other shapes may be used on bench tops, in fume hoods or in glove boxes to reduce radiation exposure from gamma-emitting radioactive materials. Similarly, shielding of low atomic number material, such as high-density plastic, may be used to reduce the exposure from high-

energy beta-emitting materials. Shielded shipping containers are frequently used for continued storage after receipt of materials.

- A particular sink should be designated for disposal of liquid radioactive waste to the sanitary sewerage system. In some cases, depending on number of users and distance between areas of use, more than one sink may need to be designated.

- Labeled waste containers should be used. These containers may be shielded as necessary, placed near the waste-generating areas and away from areas frequently occupied by personnel. Additionally, these containers should be effectively enclosed to prevent airborne contamination from radioactive materials deposited.

- Remote handling tools, such as forceps or extension handles, should be used to provide distance in the handling of radioactive materials (ALARA). In addition, shielded handling devices, such as shielded syringes, can be used to protect workers from materials that cannot be handled remotely. Pipetting should be done using appropriate devices. Pipetting by mouth should be strictly forbidden.

- Where appropriate, ventilation systems should be designed, such that, in the event of an accident, they can be shut down and isolated to contain radioactivity.

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

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

- Areas of use should be well lit to avoid spills and other accidents that could result in contamination build-up.

- Observation of activities conducted behind shielding with remote tools (or with extended arms and hands, within limits consistent with permissible occupational exposures) can be accomplished by mirrors, through shielded (e.g., leaded glass) windows, through transparent plastic beta shields, or by remote video monitoring.

- The combination of containment, shielding, and handling devices proposed for any use of radioactive materials should be appropriate to the type and quantity of materials to be used and to the type and duration of operations to be conducted.

- If respiratory protective equipment will be used to limit inhalation of airborne licensed material, follow the provisions of **12VAC5-481-810, 12VAC5-481-820,** and **12VAC5-481-830**.

Appendix M:

Audit Program - Non-Medical

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15. **AUDIT FINDINGS:**

REFERENCES

A. MANAGEMENT OVERSIGHT

1. Radiation Safety Committee

   Applicable license conditions.

2. Radiation Safety Officer

   Applicable license conditions.

3. Audits, Reviews, or Inspections

   12VAC5-481-630 Radiation protection programs.

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

   Applicable license conditions.

4. ALARA

   12VAC5-481-630 Radiation protection programs.

5. Authorized Users

   Applicable license conditions.

B. AMENDMENTS AND PROGRAM CHANGES:

   Applicable license conditions.

C. FACILITIES

1. Access Control

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

   12VAC5-481-840 Security of stored material.

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

   Applicable license conditions.

2. Engineering Controls

   12VAC5-481-630 Radiation protection programs.

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

   Applicable license conditions.

D EQUIPMENT AND INSTRUMENTATION

1. Survey Instruments

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

Applicable license conditions.

E. MATERIAL USE, CONTROL, AND TRANSFER

1. License and Applicable License Conditions.

2. Security and Control

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

3. Receipt and Transfer of Licensed Material

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

F. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

1. Area Surveys

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

Applicable license conditions.

2. Leak Tests and Inventories

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

Applicable license conditions.

G. TRAINING AND INSTRUCTIONS TO WORKERS

1 General

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

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

c. Application license conditions

H. RADIATION PROTECTION

1. Radiation Protection Program

a. Exposure evaluation

b. Programs

12VAC5-481-630 Radiation protection programs.

2 Dosimetry

a. Dose Limits

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

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

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

b. External

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

12VAC5-481-750 General.

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

Applicable license conditions.

c. Internal

12VAC5-481-670 Determination of internal exposure.

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

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

3. Records

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

12VAC5-481-1000 Records of surveys.

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

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

I. RADIOACTIVE WASTE MANAGEMENT

1. Disposal

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

12VAC5-481-910 General requirements.

12VAC5-481-1000 Records of surveys.

12VAC5-481-1060 Records of waste disposal.

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

2 Effluents

a. General

Applicable license conditions

b. Release to septic tanks

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

12VAC5-481-3690

c. Incineration of waste

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

d. Control of air effluents and ashes

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

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

12VAC5-481-750 General.

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

Applicable license conditions

3. Waste Management

a. General

12VAC5-481-910 General requirements.

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

b. Waste compacted

Applicable license conditions.

c. Waste storage areas

12VAC5-481-840 Security of stored material.

12VAC5-481-860 Posting requirements.

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

Applicable license conditions.

d. Packaging, Control, and Tracking

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

e. Transfer

12VAC5-481-910 General requirements.

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

f. Records

12VAC5-481-1000 Records of surveys.

12VAC5-481-1060 Records of waste disposal.

J. DECOMMISSIONING

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

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

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

K. TRANSPORTATION

1. General

12VAC5-481-2980 Transportation of licensed material.

2. Shippers - Requirements for Shipments and Packaging

a. General Requirements

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

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

b. Transport Quantities

12VAC5-481-10	Definitions.

i. All quantities

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

ii. Limited quantities

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

iii. Type A quantities

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

iv. Type B quantities

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

v. LSA material and SCO

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

c HAZMAT Communication Requirements

49 CFR 172.200-205	Shipping papers.

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

3. HAZMAT Training

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

4. Transportation by Public Highway

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

L. NOTIFICATIONS AND REPORTS

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

M. POSTING AND LABELING

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

Appendix N:

Reporting Requirements

Table 8: VDH Notifications and/or Reports

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

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

Appendix O:

Instrument Specifications and Model Survey Instrument and Air Sampler Calibration Programs

Radiation Monitoring Instrument Specifications

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

Table 9. Typical Survey Instruments (instruments used to measure radiological conditions at licensed facilities).

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

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

Instrument Calibration Program

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

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

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

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

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

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

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

Procedure for Calibrating Survey Instruments
A radioactive sealed source(s) used for calibrating survey instruments will:

- Approximate a point source
- Approximate the same energy and type of radiation as the environment in which the calibrated device will be employed
- For dose rate and exposure rate instruments, the source should be strong enough to give an exposure rate of at least about 7.7×10^{-6} coulombs/kilogram/hour (30 mR/hr) at 100 cm (e.g., 3.1 gigabecquerels (85 mCi) of cesium-137 or 7.8×10^{2} megabecquerels (21 mCi) of cobalt-60)

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

- Linear readout instruments with a single calibration control for all scales shall be adjusted at the point recommended by the manufacturer or at a point within the normal range of use. Instruments with calibration controls for each scale shall be adjusted on each scale. After adjustment, the response of the instrument shall be checked at approximately 20% and 80% of full scale. The instrument's readings shall be within ± 15% of the conventionally true values for the lower point and ± 10% for the upper point.
- Logarithmic readout instruments, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. The instrument shall be adjusted for each scale according to site specifications or the manufacturer's specifications. After adjustment, calibration shall be checked at a minimum of one point on each decade. Instrument readings shall have a

maximum deviation from the conventionally true value of no more than 10% of the full decade value.

- Meters with a digital display device shall be calibrated the same as meters with a linear scale.
- Readings above 2.58 x 10^{-4} coulomb/kilogram/hour (1 R/hr) need not be calibrated, but such scales should be checked for operation and response to radiation.
- The inverse square and radioactive decay law should be used to correct changes in exposure rate due to changes in distance or source decay.

Surface Contamination Measurement Instruments

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

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

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

- Approximate the geometry of the samples to be analyzed
- Approximate the same energy and type of radiation as the samples that the calibrated device will be used to measure.

Calibration

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

Calibration Records

Calibration records, for all survey instruments, should indicate the procedure used and the data obtained. The description of the calibration should include:

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

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

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

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

Air Sampler Calibration

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

The publication entitled "*Air Sampling Instruments*" found in the 7th Edition, American Conference of Governmental Industrial Hygienists, 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.

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

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

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

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

E_V: The most probable value of the cumulative percentage error in the determination of the total air volume sampled. E_V can be calculated from the following equation, provided there are no additional significant sources of errors:

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

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

A sample calculation of the most probable value of the cumulative error in total volume measured is as follows:

If accuracies of the scale reading, the calibration factor, and sample time are ± 4, 2, and 1%, respectively, and there are no other significant sources of error, the cumulative error would be:

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

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

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

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

Documentation of Calibration of Air Metering Devices

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

References:

1. NRC NUREG 1556 Vol. 18, "*Program-Specific Guidance about Service Provider Licenses*", November 2000.
2. NRC Regulatory Guide 8.25, Revision 1, "*Air Sampling in the Workplace*", June 1992.
3. NRC NUREG-1400, "*Air Sampling in the Workplace*", September 1993.
4. The Health Physics & Radiological Health Handbook, 3rd Ed. Edited by Bernard Shleien, Lester A. Slaback, Jr., and Brian Kent Birky, 1998.
5. ANSI N323A-1997, "*Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments*". Copies may be ordered electronically at the following address: <http://www.ansi.org> or obtained by contacting the American National Standards Institute, 25 West 43rd Street Fourth Floor, New York, New York 10036, Phone: 212.642.4900, Fax: 212.398.0023.
6. "*Air Sampling Instruments*", American Conference of Governmental Industrial Hygienists, 7th Edition, 1989.
7. DOE G 441.1-7, "*Portable Monitoring Instrument Calibration Guide*", U.S. Department of Energy, March 1999.
8. DOE G 441.1-8, "*Air Monitoring Guide*", U.S. Department of Energy," March 1999.

Appendix P:

Material Receipt and Accountability

Sample Procedure for Ordering and Receiving Radioactive Material

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

Sample Memorandum

Memorandum for Security Personnel

From: RSO, President, Vice President, etc.

Subject: Procedures for Receipt of Packages Containing Radioactive Material

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

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

Radiation Safety Officer (RSO): _____

Office Phone: _____

Home Phone: _____

Sample Instructions to Personnel Involved in Material Receipt

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

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

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

Name _____

Phone _____

For additional information on worker training, see the section entitled 'Training for Individuals Working In or Frequenting Restricted Areas'.

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

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

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

Sample Procedure for Safely Opening Packages Containing Licensed Materials

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

- Wear gloves to prevent hand contamination.
- Visually inspect the package for any sign of damage (e.g. crushed, punctured). If damage is noted, stop and notify the RSO.
- Check DOT White I, Yellow II, or Yellow III label or packing slip for activity of contents, so shipment does not exceed license possession limits.
- Monitor the external surfaces of a labeled package according to specifications in **12VAC5-481-900**.
- Open the outer package (following supplier's directions if provided) and remove packing slip.
- Open inner package to verify contents (compare requisition, packing slip and label on the bottle or other container).
- Check integrity of the final source container (e.g., inspecting for breakage of seals or vials, loss of liquid, discoloration of packaging material, high count rate on smear). Check again that the shipment does not exceed license possession limits. If you find anything other than expected, stop and notify the RSO.
- Survey the packing material and packages for contamination before discarding. If contamination is found, treat as radioactive waste. If no contamination is found, obliterate the radiation labels prior to discarding in the regular trash.
- Maintain records of receipt, package survey, and wipe test results.
- Notify the final carrier and, by telephone, and either telegram, or facsimile, the Virginia Department of Health, when removable radioactive surface contamination exceeds the limits of **12VAC5-481-3080**; or external radiation levels exceed the limits of **12VAC5-481-3080**.

Sample Transfer Policy Statements

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

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

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

References: DOE G 441.13-1, "*Sealed Radioactive Source Accountability and Control*", U.S. Department of Energy, April 1998.

Appendix Q:

Methodology for Determining Public Dose

Doses to Members of the Public

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

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 millisievert (mSv) [100 millirem (mrem)] in one calendar year resulting from the licensee's possession and/or use of licensed materials.
- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.
- Air emissions of radioactive materials do not result in doses greater than 0.1 mSv (10 mrem) Total Effective Dose Equivalent (TEDE).

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

Doses to Members of the Public
INCLUDES doses from:

- Radiation and/or radioactive material released by a licensee
- Sources of radiation under the control of a licensee
- Air effluents from sources of licensed radioactive materials
- Licensed material in transportation or storage at the licensee's facility

BUT, DOES NOT INCLUDE doses from:

- Sanitary sewerage discharges from licensees
- Natural background radiation
- Medical administration of radioactive material
- Voluntary participation in medical research

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

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

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

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

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

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

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

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

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

The public dose limit applies to the individual who is likely to receive the highest dose from licensed operations. Therefore, the dose calculations must consider the location with the potential for the highest internal and external exposures. An extremely conservative calculation would assume that the individual was continuously present 24 hours a day, 365 days a year, or an occupancy factor of 1 (see **Table 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, however, the licensee would rather choose a more realistic assumption of the individual's occupancy at the points of highest internal and external exposures, then the licensee may use the occupancy factors in **Table 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.

Appendix R:

General Topics for Safe Use of Radioisotopes and Emergency Procedures

General Topics for Safe Use of Radioisotopes

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

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

Radionuclides-specific Procedures

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

Example 1:

If requesting more than 37 MBq (1 mCi) of iodine-125 or iodine-131, special safety instructions should be provided to users, 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.
- 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
- The use of eye protection for procedures that involve 10 millicuries or more.

Emergency Procedures

General Safety Procedures to Handle Spills

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

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

Minor Spills of Liquids and Solids

- **Instructions to Workers**

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

- **Reminders to RSO**

- Follow up on the decontamination activities and document the results.
- As appropriate, determine cause and corrective actions needed; consider bioassays, if there is a potential for internal contamination.
- If necessary, notify VDH.

Major Spills of Liquids and Solids

- **Instructions to Workers**

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

• **Reminders to RSO**

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

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

• **Instructions to Workers**

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

• **Reminders to RSO**

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

Minor Fires

- **Instructions to Workers**

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

- **Reminders to RSO**

- 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 is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document incident.
- If necessary, notify VDH.

Fires, Explosions, or Major Emergencies

- **Instructions to Workers**

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

- **Reminders to RSO**

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

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

Procedures for Collecting Bioassay Samples

In the event of an emergency where an individual may become contaminated and radioactive material was taken into the body through skin absorption or other means, or is suspected of having ingested or inhaled radioactive material, an estimate of the amount of material taken into the body may be required. The following items should be considered in developing your procedures:

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

Appendix S:

Radiation Surveys

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

Training

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

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

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

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

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

Facilities and Equipment

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

Ambient Radiation Level Surveys

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

Contamination Surveys

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

Contamination surveys should be performed:

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

Contamination Survey Frequency

Personnel should survey for contamination in locations where individuals are working with an unsealed form of radioactive material in an amount greater than or equal to 10% of the smallest annual limit on intake (ALI) (either the inhalation or ingestion ALI) listed for that radionuclide in **12VAC5-481-3690**. These surveys should be done at a frequency appropriate to the types and quantities of radioactive materials in use, but, at a minimum, quarterly. If amounts are used that are greater than or equal to the smallest ALI listed for that radionuclide in **12VAC5-481-3690**, detailed, documented, surveys should be performed at least monthly.

Table 11 contains suggested contamination survey frequency from NRC Regulatory Guide 8.23 (See **Tables 12, 13,** and **14** for alternate survey frequencies).

Table 11: Suggested Frequency of Contamination Surveys from NRC Regulatory Guide 8.23

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

Alternate Survey Frequency

Classification of Laboratories

Table 12: Survey Frequency Category

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

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

Table 13: Survey Frequency Category Modifiers

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

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

Survey Frequency:

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

Table 14: Isotope Groups

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

Contamination in Unrestricted Areas

Contamination found in unrestricted areas should be immediately decontaminated to background levels. When it is not possible to get to background levels, the licensee must ensure that the amounts do not exceed the contamination levels listed in **Table 15**.

Table 15. Acceptable Surface Contamination Levels

Nuclide[1]	Average[2, 3]	Maximum[2, 4]	Removable[2, 5]
I-125, I-129	1.7 Bq/100 cm^2 (100 dpm/100 cm^2)	5.0 Bq/100 cm^2 (300dpm/100cm^2)	0.3 Bq/100 cm^2 (20 dpm/100 cm^2)
I-126, I-131, I-133, Sr-90	16.7 Bq/100 cm^2 (1,000 dpm/100 cm^2)	50.0 Bq/100 cm^2 (3,000 dpm/100 $cm^{2)}$	3.3 Bq/100 cm^2 (200 dpm/100 cm^2)
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	83.3 Bq/100 cm^2 (5,000 dpm/100 cm^2)	250 Bq/100 cm^2 (15,000 dpm /100 cm^2)	6.7 Bq/100 cm^2 (1,000 dpm/100 cm^2)

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

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

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

Survey Record Requirements

Each survey record should include the following:

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

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

Air Monitoring in the Workplace

Air monitoring can be used to do the following:

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

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

Refer to NRC Regulatory Guide 8.25, Revision 1, "*Air Sampling in the Workplace*", 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 VDH 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, the number of procedures performed, or other appropriate methods. The unmonitored effluents should not exceed 30% of the total estimated effluent releases or 10% of the permissible air effluent concentrations found in column 1 of Table 2 in **12VAC5-481-3690**, whichever is greater.

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

Liquid Effluent Release Monitoring

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

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

Bioassay Monitoring

Frequency of Required Bioassay Measurements

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

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

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

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

Routine Measurements

Routine measurements include baseline measurements, periodic measurements, and termination measurements. These measurements should be conducted to confirm that appropriate controls exist and to assess dose. The method of bioassay selected (for example, whole body counting, urinalysis, etc.) and the samples collected will vary according to the radionuclides and the compound to which it is attached. Sample collection procedures should be developed to ensure that appropriate types, sizes, and numbers of samples are collected that will provide appropriate physiological information for the dose assessment. An individual's baseline measurement of radioactive material within the body should be conducted before beginning work that involves exposure to radiation or radioactive materials for which monitoring is required.

In addition to the baseline measurements, periodic bioassay measurements should be performed. The frequency of periodic measurements should be based on the likelihood of significant exposure of the individual. In determining the worker's likely exposure, consider such information as the worker's access, work practices, measured levels of airborne radioactive material, and exposure time. Periodic measurements should be made when the cumulative exposure to airborne radioactivity since the most

recent bioassay measurement is > 0.02 ALI (40 DAC hours). Noble gases and airborne particulates with a radioactive half-life of less than 2 hours should be excluded from the evaluation, since external exposure generally controls these radionuclides.

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

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

Special Monitoring

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

When determining whether potential intakes should be evaluated, consider the following circumstances:

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

References:

1. NRC Regulatory Guide 4.20, "*Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors*", dated December 1996.
2. NRC Regulatory Guide 8.9, Revision 1, "*Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program*", dated July 1993.
3. NRC Regulatory Guide 8.23, Revision 1, "*Radiation Safety Surveys at Medical Institutions*", dated January 1981.
4. NRC Regulatory Guide 8.25, Revision 1, "*Air Sampling in the Workplace*", dated June 1992.
5. NRC Regulatory Guide 8.32, "*Criteria for Establishing a Tritium Bioassay Program*", dated July 1988.
6. NRC Regulatory Guide 8.37, "*ALARA Levels for Effluents from Materials Facilities*", dated July 1993.
7. NRC NUREG-1400, "*Air Sampling in the Workplace*", dated September 1993.
8. NRC NUREG/CR- 4884, "*Interpretation of Bioassay Measurements*", dated July 1987.
9. ANSI N13.1 (1969), "*Document to Sampling Airborne Radioactive Materials in Nuclear Facilities*", dated 1991.
10. ANSI N13.30-1996, "*Performance Criteria for Radiobioassay*", dated 1996.
11. ANSI N42.18, "*Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents*", 1991.
12. NCRP Commentary No. 3, "*Screening Techniques for Determining Compliance with Environmental Standards*", published in January, 1989, and the addendum published in October, 1989.
13. U.S. Department of Energy, DOE G 441.1-8, "*Air Monitoring Guide*", March 17, 1999.
14. U.S. Department of Energy, DOE G 441.1-3, "*Internal Dosimetry Program Guide*", March 17, 1999.
15. U.S. Department of Energy, DOE G 441.1-4, "*External Dosimetry Program Guide*", March 17, 1999.
16. U.S. Department of Energy, DOE G 441.1-2, "*Occupational ALARA Program Guide*", March 17, 1999.

Appendix T:

Leak Test Procedures

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

Frequency for Conducting Leak Tests of Sealed Sources

Leak tests will be conducted at the frequency specified in the respective SSD Registration Certificate.

Procedure for Performing Leak Testing and Analysis

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

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

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

where:

cpm = counts per minute
std = standard
bkg = background
Bq = becquerels

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

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

- Sign and date the list of sources, data and calculations. Retain records for 5 years **(12VAC5-481-1010).**
- If the wipe test activity is 185 Bq (0.005 mCi) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly.
- Notify VDH.

Appendix U:

Transportation Requirements

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

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

Hazard Communications for Class 7 (Radioactive) Materials

DOT Shipping Papers (49 CFR 172.200-205)

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

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

Some Special Considerations/Exceptions for Shipping Paper Requirements

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

Hazard Communications for Class 7 (Radioactive) Materials

Marking Packages (49 CFR 172.300-338)

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

Markings Always Required Unless Excepted

Non-Bulk Packages

- Proper shipping name
- U.N. identification number
- Name and address of consignor or consignee, *unless*:
  1. highway only and no motor carrier transfers; *or*
  part of carload or truckload lot or freight container load, and entire contents of railcar, truck, or freight container are shipped from one consignor to one consignee [see §172.301(d)]

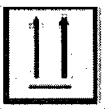
Bulk Packages (i.e., net capacity greater than 119 gallons as a receptacle for liquid, or 119 gallons and 882 pounds as a receptacle for solid, or water capacity greater than 1000 lbs, with no consideration of intermediate forms of containment)

- U.N. identification number, on orange, rectangular panel (see §172.332) - some exceptions exist

Additional Markings Sometimes Required

Materials-Based Requirements

- If in excess of 110 lbs (50 kg), Gross Weight
- If non-bulk *liquid* package, underlined double arrows indicating upright orientation (two opposite sides) [ISO Std 780-1985 marking]



- If a Hazardous substance in non-bulk package, the letters "RQ" in association with the proper shipping name

Package-Based Requirements

- The package type if Type A or Type B (½" or greater letters)
- The specification-required markings [e.g., for Spec. 7A packages: "DOT 7A Type A" and "Radioactive Material" (see §178.350-353)]
- For approved packages, the certificate ID number (e.g., USA/9166/B(U), USA/9150/B(U)-85, ...)
- If Type B, the trefoil (radiation) symbol per Part 172 App. B [*size*: outer radius ≥ 20 mm (0.8 in)]
- For NRC certified packages, the model number, gross weight, and package ID number (10 CFR 71.85)

Administrative-Based Requirements

- If a DOT exemption is being used, "DOT-E" followed by the exemption number
- If an export shipment, "USA" in conjunction with the specification markings or certificate markings

Optional Markings

- "IP-1," "IP-2," or "IP-3" on industrial packaging is recommended
- Both the name and address of consignor and consignee are recommended
- Other markings (e.g., advertising) are permitted, but must be sufficiently away from required markings and labeling

Some Special Considerations/Exceptions for Marking Requirements

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

Hazard Communications for Class 7 (Radioactive) Materials

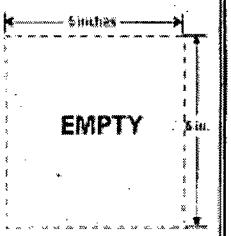
Labeling Packages (49 CFR 172.400-450)

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

Placement of Radioactive Labels

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

Determination of Required Label

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

Content on Radioactive Labels

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

Some Special Considerations/Exceptions for Labeling Requirements

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

Hazard Communications for Class 7 (Radioactive) Materials

Placarding Vehicles (49 CFR 172.500-560)

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

Visibility and Display of Radioactive Placard

- Placards are required to be displayed:
  - On four sides of the vehicle;
  - Visible from the direction they face, (for the front side of trucks, tractor-front, trailer, or both are authorized);
  - Clear of appurtenances and devices (e.g., ladders, pipes, tarpaulins);
  - At least 3 inches from any markings (such as advertisements) which may reduce placard's effectiveness;
  - Upright and on-point such that the words read horizontally;
  - In contrast with the background, or have a lined-border which contrasts with the background;
  - Such that dirt or water from the transport vehicle's wheels will not strike them;
  - Securely attached or affixed to the vehicle, or in a holder.
- Placard must be maintained by carrier to keep color, legibility, and visibility.

Conditions Requiring Placarding

- Placards are required for any vehicle containing a package with a RADIOACTIVE Yellow-III label.
- Placards are required for shipment of LSA or SCO required by §173.427 to be consigned as exclusive use. Examples of this category are domestic, strong-tight containers with less than an A_2 quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52. Also, for bulk packages of these materials, the orange panel marking with the UN Identification number is not required.
- Placards are required for any vehicle containing a package with a Highway Route Controlled Quantity (HRCQ). In this case, the placard must be placed in a square background as shown below (see §173.507(a)).

Radioactive Placard

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

Minimum Required Packaging For Class 7 (Radioactive) Materials

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

Quantity:	< 70 Bq/g (< 0.002 μCi/g)	Limited Quantity (§173.421)		A_1/A_2 value (§173.435)	1 rem/hr at 3 m, un-shielded (§173.427)
Non-LSA/SCO:	**Excepted**	**Type A**		**Type B [3]**	
Domestic or International LSA/SCO: • LSA-I solid, (liquid)[1] • SCO-I	Excepted	IP-I			Type B [3]
• LSA-I Liquid • LSA-II Solid, (liquid or gas)[1] • (LSA-III)[1] • SCO-II		IP-II			Type B [3]
• LSA-II Liquid or Gas • LSA-III		IP-III			Type B [3]
Domestic (only) LSA/SCO: • LSA-I, II, III; SCO-I, II	Excepted	Strong-tight [2]	DOT Spec. 7A Type A		Type B [3] NRC Type A LSA [3,4]

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

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

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

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

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

Package and Vehicle Contamination Limits (49 CFR 173.443)

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

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

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

The Basic Contamination Limits for All Packages: 49 CFR 173.443(a), Table 11	
	General Requirement: Non-fixed (removable) contamination must be kept as low as reasonably achievable (ALARA)
	$\beta\gamma$: 0.4 Bq/cm^2 = 40 Bq/100 cm^2 = 1×10^{-5} µCi/cm^2 = 2200 dpm/100 cm^2
	α: 0.04 Bq/cm^2 = 4 Bq/100 cm^2 = 1×10^{-6} µCi/cm^2 = 220 dpm/100 cm^2

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

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

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

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

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

_____

(Signed) Radiation Safety Officer

Appendix V:

Sample Waste Management Procedures

General Guidelines

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

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

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

1. Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.
2. Short-lived waste should be segregated from long-lived waste.
3. Waste should be stored in suitable well-marked containers and the containers should provide adequate shielding.
4. Liquid and solid wastes must be stored separately.
5. When the container is full, it should be sealed. The sealed container should be identified with a label affixed or attached to it.
6. The identification label should include the date when the container was sealed, the longest-lived radioisotope in the container, total activity, date when ten half-lives of the longest-lived radioisotope will have transpired, and the initials of the individual who sealed the container. The container may be transferred to the DIS area. When large quantities are held for DIS, sufficient quantities may be present even after 10 half-lives that individuals performing surveys should be aware of the potential for measurable radiation.
7. The contents of the container should be allowed to decay for at least ten half-lives of the longest-lived radioisotope in the container.
8. Prior to disposal as ordinary trash, each container should be monitored as follows:
   a) Check the radiation detection survey meter for proper operation.
   b) Survey the contents of each container in a low background area.
   c) Remove any shielding from around the container.
   d) Monitor all surfaces of the container.
   e) Discard the contents as ordinary trash only if the surveys of the contents indicate no residual radioactivity (i.e. surface readings are indistinguishable from background).

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

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

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

Sample Procedure for Disposal of Liquids into Sanitary Sewerage

1. Confirm that the sewer system is a public system, not a private sanitary sewer, septic system, or leach field.
2. Confirm that the liquid waste being discharged is soluble (or is biological material that is readily dispersible) in water.
3. Calculate the amount of each radioisotope that can be discharged by using the information from prior, similar discharges and the information in **12VAC5-481-3690**.
4. Make sure that the amount of each radioisotope does not exceed the monthly and annual discharge limits specified in **12VAC5-481-930** and **12VAC5-481-3690** (records for individual users/laboratories).
5. If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit in **12VAC5-481-3690** must not exceed unity.
6. Total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 185 GBq (5 Ci) of H-3 (tritium), 37 GBq (1 Ci) of C-14, and 37 GBq (1 Ci) of all other radioisotopes combined.
7. Record the date, radioisotope(s), estimated activity of each radioisotope, location where the material is discharged, and the initials of the individual discharging the waste.
8. Liquid waste should be discharged only via designated sinks or toilets.
9. Discharge liquid waste slowly to minimize splashing with water running, to be sure that the material moves out of the sink and into the sewer system.
10. Survey the sink and surrounding work surfaces to confirm that no residual material or contamination remained in the sink or on work surfaces. Decontaminate as appropriate.
11. Decontaminate all areas or surfaces if found to be contaminated.
12. For all releases to the sanitary sewer from the licensed facility, maintain records of each radioisotope and its quantity and concentration that is released into the sewer system that demonstrate compliance with the regulatory limits for total quantity released and concentrations released by the licensed facility.

Sample Procedure for Incineration

These guidelines apply to noncommercial waste disposal, i.e., incineration of a licensee's own waste. You do not need specific VDH approval in order to incinerate certain categories of radioactive waste. For example, **12VAC5-481-950** provides that tritium and carbon-14 in low level concentrations in liquid scintillation media and animal tissue may be disposed of without regard to radioactivity.

After you review your program and confirm that you have waste that requires specific VDH approval for incineration, please provide the following information:

1. Describe the training and experience of the person who will be responsible for the on-site and day-to-day supervision of incinerator operations.
2. Describe the waste that is proposed to be incinerated, to include: the chemical and/or physical form of the waste containing licensed material and a description of how the waste is segregated, packaged, and labeled for transfer from the generation site to the incinerator; the name of the radioisotope; concentration of radioactivity averaged over the weight of the material to be incinerated (microcuries per gram of waste medium) for each isotope to be incinerated; and the total radioactivity of each isotope per burn and the total number of burns per year. Describe procedures for ensuring that these frequencies and activities will not be exceeded.
3. Describe the procedures for packaging, handling, securing, and monitoring of waste to prevent contamination and/or unnecessary exposure to personnel or property during the waste life cycle.
4. Describe your method for measuring or estimating the concentration of radioactive material remaining in the ash residue. Describe your procedures for collection, handling, and disposal of the ash residue.
5. Describe the recordkeeping procedures for the waste incineration program. Records must be adequate to document all receipts, incinerations, environmental releases of effluents, and any disposals of ash generated in the incineration process. These records must be maintained in the same units as applicable rules.
6. Describe the characteristics of the incinerator and site location, including: height of the stack, rated air flow (cubic feet per hour or similar units), proximity of the stack or other discharge to occupied areas (e.g., residences, school, hospital), and distance to the nearest air intake ducts of adjacent buildings. Describe any scrubbers, filters, or air cleaning equipment that is present.
7. State how the concentration of radionuclides released, both as airborne effluent and as any liquid effluent from scrubbers, condensers, or associated systems, will be measured or otherwise determined. Describe any stack monitoring that is planned.
8. Provide a copy of the written safety analysis that demonstrates the applicant will be able to incinerate the types and quantities of radioactivity specified in the application without exceeding the environmental release limits specified in **12VAC5-481 'Virginia Radiation Protection Regulations'**.
9. Provide a written commitment that the applicant has coordinated with appropriate state and local authorities and that such permits and other authorizations, as may be necessary, have been obtained.
10. Provide a copy of the radiation safety procedures for monitoring personnel involved in incineration operations and for monitoring all effluent generated by the incineration process. The procedures must ensure that regulatory limits for environmental releases of radioactivity will not be exceeded. The applicant must describe how any ash generated exceeding regulatory limits will be disposed of.

Compaction of Waste

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

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

3. Provide an analysis of the potential for airborne release of radioactive material during compaction activities.
4. State the location of the compactor(s) within the waste processing area(s), as well as a description of the ventilation and filtering systems used in conjunction with the compactors. Include a description of the procedures for monitoring filter blockage and exchange.
5. Discuss the methods used to monitor worker breathing zones and/or exhaust systems.
6. Discuss the types and frequencies of surveys that will be performed for contamination control in the compactor area.
7. Discuss the instruction provided to compactor operators, including instructions for protective clothing; checks for proper functioning of equipment; method of handling un-compacted waste; and examining containers for defects.

Commonwealth of Virginia
Radiation Protection Regulatory Guide

Guidance for Commercial Radiopharmacy

EPI-720 I

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

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

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

This VAREG, 'Guidance for Commercial Radiopharmacy' has been developed to streamline the application process for a commercial radiopharmacy license. A copy of the VDH form 'Application for a Radioactive Material License for Commercial Radiopharmacies' is located in **Appendix A** of this guide.

Appendixes 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 **12VAC5-491** for a commercial radiopharmacy.

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

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

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

  Please identify all attachments with the applicant's name and license number (if a renewal).
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original signed application along with attachments (if any).
- Submit the application fee (for new licenses only).
- Retain one copy of the licensee application and attachments (if any) for your future reference. You will need this information because the license will require that radioactive material be possessed and used in accordance with statements, representation, and procedures provided in the application and supporting documentation.

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

CONTENTS

APPENDICES

TABLES

FIGURES

ABBREVIATIONS

ALARA	as low as is reasonably achievable
ALI	annual limit on intake
ANP	authorized nuclear pharmacist
ANSI	American National Standards Institute
AU	authorized user
bkg	background
BPR	business process redesign
Bq	becquerel
CDE	committed dose equivalent
CEDE	committed effective dose equivalent
CFR	Code of Federal Regulations
Ci	curie
cc	centimeter cubed
cm	centimeter
cm^2	centimeter squared
cpm	counts per minute
DAC	derived air concentration
DDE	deep-dose equivalent
DFP	decommissioning funding plan
DIS	decay in storage
DOE	United States Department of Energy
DOT	United States Department of Transportation
dpm	disintegrations per minute
dpm/cm^2	disintegrations per minute per square centimeter
EDE	effective dose equivalent
FA	financial assurance
FDA	United States Food and Drug Administration
GM	Geiger-Mueller
GPO	Government Printing Office
IN	Information Notice
IP	Inspection procedure
mCi	milliCurie
mGy	MilliGray
MDA	Minimum detectable activity
MOU	Memorandum of Understanding
mR	Milliroentgen
mrem	Millirem
mrem/hr	millirem per hour
mSv	Millisievert
mSv/hr	millisievert per hour
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NMSS	Office of Nuclear Materials Safety and Safeguards
NRC	Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OSL	Optically Stimulated Luminescence
PET	Positron Emission Tomography

P&GD	Policy and Guidance Directive
QA	quality assurance
R	roentgen
RG	Regulatory Guide
RQ	reportable quantity
RSO	radiation safety officer
SDE	Shallow-dose equivalent
SI	International System of Units (abbreviated SI from the French, Le Systeme Internationale d'Unites)
SSDR	Sealed Source and Device Registration
std	Standard
Sv	Sievert
TAR	Technical assistance request
TEDE	Total effective dose equivalent
TI	Transportation index
TLD	Thermoluminescent dosimeters
USDA	United States Department of Agriculture
VDH	Virginia Department of Health
µCi	microcurie
%	percent

PURPOSE OF GUIDE

This document provides guidance to an applicant in preparing a license application for a commercial radiopharmacy license. It also provides guidance on VDH's criteria for evaluating a commercial radiopharmacy license application. Within this guide, the terms, "commercial radiopharmacy," "radiopharmacy," "nuclear pharmacy," and "pharmacy" are used interchangeably.

Commercial radiopharmacy licenses are those licenses issued by VDH, pursuant to **12VAC5-481-480** for the possession and use of radioactive materials for the manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under **12VAC5-481-1670** through **12VAC5-481-2080**. Within this guide, preparation includes the making of radiopharmaceuticals from reagent kits (i.e., technetium-99m MAA (macroaggregated albumin)), and from raw materials (i.e., PET radiopharmaceuticals, the compounding of radioiodine capsules for diagnostic and therapeutic medical use). Commercial radiopharmacies may also be authorized to transfer for commercial distribution *in vitro* test kits described in **12VAC5-481-430 G**, radiopharmaceuticals to licensees authorized to possess them for other than human medical use (i.e., veterinary medicine and research licensees), and radiochemicals to those licensees authorized to possess them, pursuant to **12VAC5-481-430** and **12VAC5-481-500**. In addition, **12VAC5-481-480** authorizes radiopharmacies to redistribute (transfer) sealed sources for calibration and medical use initially distributed by a manufacturer licensed pursuant to **12VAC5-481-480**.

Specific guidance for applicants requesting to manufacture and initially distribute molybdenum-99/technetium-99m generators, *in vitro* kits, radiochemicals and sealed sources is included in NRC NUREG 1556, Vol. 12, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Manufacturing and Distribution Licenses', and is not within the scope of this VAREG. These activities require specific VDH, NRC or another Agreement State authorization and must be included on a specific license.

Furthermore, specific guidance for applicants requesting authorization to manufacture, distribute, and redistribute radioactive drugs to persons exempt from licensing (i.e., carbon-14 tagged urea)

is included in NRC NUREG - 1556, Vol. 8, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Exempt Distribution Licenses', and also is not within the scope of this guidance.

This VAREG describes the information needed to complete VDH form, 'Application for a Radioactive Material License for Commercial Radiopharmacies' (**Appendix A**).

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

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

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

In this guide, "dose" or "radiation dose" means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent (TEDE). These terms are defined in **12VAC5-481-10**. Rem and Sievert, its SI equivalent (1 rem = 0.01 Sv), are used to describe units of radiation exposure or dose. This is done because **12VAC5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation',** sets dose limits in terms of rem, not rad or roentgen. Furthermore, radioactive materials commonly used in medicine emit beta and photon radiation, for which the quality factor is 1; a useful rule of thumb is an exposure of 1 roentgen is equivalent to an absorbed dose of 1 rad and dose equivalent of 1 rem. Determination of dose equivalent (rem) from absorbed dose (rad) from alpha particles requires the use of an appropriate quality factor (Q) value. Q values are used to convert absorbed dose (rad) to dose equivalent (rem). Q values for alpha particles are addressed in the **12VAC5-481-240.**

This VAREG provides the latest guidance and is modeled on the Nuclear Regulatory Commission's (NRC) NUREG 1556, Volume 13. The VAREG shows the requirements in terms of the **12VAC5-481 'Virginia Radiation Protection Regulations'** and provides a user-friendly format to assist with the preparation of commercial radiopharmacies application.

LICENSES

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

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

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

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

12VAC5-481-630, Radiation protection programs, states that *"each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities"* and *"the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are...ALARA."* This section also requires that licensees review the content of the radiation protection program and its implementation annually.

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 pharmacy 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-1556, Vol 13 'Program-Specific Guidance About Commercial Radiopharmacy Licenses'.

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

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

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

WHO REGULATES FACILITIES IN THE COMMONWEALTH OF VIRGINIA?

In the special situation of work at federally controlled sites in the Commonwealth of Virginia, it is necessary to know the jurisdictional status of the land to determine whether 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 regulation authority.

Table 1: Who Regulates the Activity?

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

A current list of Agreement States (states that have entered into agreements with the NRC that give them the authority to license and inspect radioactive material used or possessed within their borders), including names, addresses, and telephone numbers of responsible officials are

maintained by the NRC Office of Federal and State Materials and Environmental Management Programs and is available on their website: http://nrc-stp.ornl.gov/.

MANAGEMENT RESPONSIBILITY

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

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

To ensure adequate management involvement, a management representative (i.e., chief executive officer or delegate) must sign the submitted application acknowledging management's commitments to and responsibility for all 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;
- Approval of qualified individual(s) to serve as 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 C**.

APPLICABLE RULE

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

The following parts of **12VAC5-481 'Virginia Radiation Protection Regulations'** contain requirements applicable to Commercial Radiopharmacy licenses.

- Part I: 'General Provisions'
- Part III: 'Licensing of Radioactive Materials'
- 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/Epidemiology/RadiologicalHealth/.

HOW TO FILE

Applicants for a materials license should do the following:

- Be sure to use the current guidance from VDH in preparing an application.
- Complete VDH form, 'Application for a Radioactive Material License for Commercial Radiopharmacies'. (**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 11inch 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.

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 the agency.

WHERE TO FILE

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

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

LICENSE FEES

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

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

Direct all questions about VDH's fees or completion of **Item 16** of VDH form, 'Application for a Radioactive Material License for Commercial Radiopharmacies' *(***Appendix A**) to **Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, Virginia 23219 or (804) 864-8150.**

CONTENTS OF AN APPLICATION

Item 1: Type of Application

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

Response from Applicant:

Item 1 Type Of Application (Check One Box)
☐ New License ☐ Renewal License Number _____

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: VDH 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: 12VAC5-481-330; 12VAC5-481-400, 12VAC5-481-480, 12VAC5-481-490 B; 12VAC5-481-500

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

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

- Radioactive materials are possessed, used, or controlled only by persons who have valid VDH 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 radioactive material;
- Public health and safety are not compromised by the use of such materials.

Notification of Bankruptcy Proceedings

Rule: 12VAC5-481-500

Criteria: 12VAC5-481-500 requires the licensee to notify VDH in writing immediately upon 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.

Item 3: Person to Contact Regarding Application

Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the proposed radiation safety officer, unless the applicant has named a different person as the contact. The agency will contact this individual if there are questions about the application.

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

Applicants should note that deviations from the suggested responses and submission of alternative procedures may require custom review.

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: **12VAC5-481-500**

Criteria: Applicants need to provide a description of storage and use location.

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

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 in the section 'Financial Assurance and Record Keeping for Decommissioning', licensees need to maintain permanent records on file describing where radioactive material was used or stored while the license was in effect. 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 radioactive 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)

Item 5: Radiation Safety Officer (RSO)

Rule: 12VAC5-481-440; 12VAC5-481-450; 12VAC5-481-480; 12VAC5-481-500

Criteria: Each licensee must appoint a qualified individual to act as the Radiation Safety Officer (RSO). The RSO must have adequate training and experience.

Discussion: VDH holds the licensee responsible for the radiation protection program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Senior management should delegate to the RSO, in writing, sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding **12VAC5-481 'Virginia Radiation Protection Regulations'**, license provisions and to terminate unsafe activities involving radioactive material. The applicant shall submit an organizational chart describing the management structure, reporting paths, and the flow of authority between executive management and the RSO. Management may delegate authority to the RSO to submit license amendments.

VDH requires the name, training, and experience of the proposed RSO to ensure that the applicant has identified a responsible qualified person to oversee the radiation safety program. When selecting an RSO, the applicant should keep in mind the duties and responsibilities of the position and select an individual who is qualified, and has the time and resources, to fulfill those duties and responsibilities. Typical duties and responsibilities of a radiopharmacy RSO are included in **Appendix H**.

The RSO needs a level of basic technical knowledge sufficient to understand the work to be performed with radioactive materials at the radiopharmacy and to be qualified by training and experience to perform the duties required for that position. Any individual who has sufficient training and experience to be named as an Authorized Nuclear Pharmacist (ANP) is also considered qualified to serve as the facility RSO. The same is true for an Authorized User (AU) who has had adequate training and experience in the radiation safety aspects associated with the use of similar types of radioactive material.

The training and experience requirements for the RSO may be met by any of the following:

- Qualification as an ANP;
- Identification as an AU on the license and experience in the use of the types and quantities of radioactive material for which the individual has RSO responsibilities; or
- Didactic and work experience.

In order 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 all the following subjects:

- Radiation protection principles;
- Characteristics of ionizing radiation;
- Units of radiation dose and quantities;
- Radiation detection and measurement instrumentation;
- Biological hazards of exposure to radiation (appropriate to types and forms of radioactive material to be used);
- VDH requirements and standards; and
- Hands-on use of radioactive materials commensurate with the uses proposed by the applicant.

The length of training and experience will depend upon the type, form, quantity, and proposed use of the radioactive material requested. The proposed RSO's training and experience should be sufficient to identify and control the anticipated radiation hazards. The requisite training may be obtained from formal courses consisting of lectures and laboratories designed for RSOs presented by academic institutions, commercial radiation safety consulting companies, or appropriate professional organizations. Each hour of training may be counted only once and should be allocated to the most representative topic.

On-the-job training may not be counted toward the hours documenting length of training unless it was obtained as part of a formal training course. A 'formal' training course is one that incorporates the following elements:

- A detailed description of the content of the course is maintained on file at the sponsoring institution and can be made available to the agency upon request;
- Evidence that the sponsoring institution has examined the student's knowledge of the course content is maintained on file at the institution and can be made available to the agency upon request. This evidence of the student's overall competency in the course material should include a final grade or percentile; and
- A permanent record that the student successfully completed the course is kept at the institution.

Response from Applicant:

Item 5 Radiation Safety Officer (RSO) (Check all that apply and attach evidence of training and experience)
NAME_____ TELEPHONE NUMBER _____
(Include area code)

☐ We will submit an organizational chart describing the management structure, reporting paths, and the flow of authority between executive management and the RSO

AND EITHER

☐ A copy of the license (VDH, the NRC or another Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO, an Authorized Nuclear Pharmacist, or an Authorized User;

OR

☐ A description of the training and experience demonstrating that the proposed RSO is qualified by training and experience as applicable to commercial nuclear pharmacies. Appendix G in VAREG 'Guidance for Commercial Radiopharmacy' should be used in documenting and determining required training and experience.

Note: See **Appendix G** for convenient formats to use for documenting hours of training in basic radioisotope handling techniques and hours of experience using radioisotopes.

Item 6: Authorized Nuclear Pharmacist (ANP)

Rule: 12VAC5-481-10; 12VAC5-481-440, 12VAC5-481-450 A; 12VAC5-481-480; 12VAC5-481-1690; 12VAC5-481-1710; 12VAC5-481-1770; 12VAC5-481-1780; 12VAC5-481-1790

Criteria: ANP must be a state-licensed pharmacist with adequate training and experience.

Discussion: Each commercial nuclear pharmacy must have an ANP to prepare or supervise the preparation of radioactive drugs for medical use. Any individual who is not qualified to be an ANP may work under the supervision of an ANP.

The criteria for a pharmacist to work as an ANP at a commercial radiopharmacy are described in **12VAC5-481-480 I**. This section of the rule refers to the definition of an ANP in **12VAC5-481-10**, training and experience criteria described in **12VAC5-481-1770**, and recentness criteria described in **12VAC5-481-1790**. Successful completion of training as described in **12VAC5-481-1790**, within 7 years proceeding the date of the application, is evidence of adequate training and experience. Additional training and experience may be necessary if the time interval is greater than 7 years. Applicants may find it convenient to present this documentation using formats similar to those found in **Appendix G**. Each hour of training may be listed only once (i.e., under the most applicable category). The recentness of training requirements applies to board certification as well as to other recognized training pathways.

On-the-job training may not be counted toward the hours listed above unless it was obtained as part of a formal training course. A 'formal' training course is one that incorporates the following elements:

- A detailed description of the content of the course is maintained on file at the sponsoring
  facility or institution and can be made available to the agency upon request;
- Evidence that the sponsoring facility or institution has examined the student's knowledge of
  the course content is maintained on file at the institution and can be made available to the
  the agency upon request. This evidence of the student's overall competency in the course
  material should include a final grade or percentile; and

- A permanent record that the student successfully completed the course is kept at the facility or institution.

Response from Applicant:

Item 6 Authorized Nuclear Pharmacist (ANP) (Check all that apply and attach evidence of training and experience)

☐ We will provide a copy of the State pharmacy licensure for each pharmacist.

AND ONE OF THE FOLLOWING

☐ We will provide a copy of the license (VDH, the NRC or another Agreement State) on which the individual was specifically named as an ANP.

OR

☐ We will provide a copy of the permit maintained by a broad scope licensee or NRC master material licensee.

OR

☐ We will provide a copy of the certification(s) for the radiopharmacy board(s), and e will provide a written certification, signed by a preceptor ANP, that the training and experience as specified in **12VAC5-481-1770** has been completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

OR

☐ We will provide a description of the training and experience demonstrating that the proposed ANP is qualified by training and experience, and we will provide a written certification, signed by a preceptor ANP, that the training and experience as specified in **12VAC5-481-1770** has been completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

Item 7: Authorized Users (AU)

Rule: 12VAC5-481-10; 12VAC5-481-440; 12VAC5-481-450 A; 12VAC5-481-1690; 12VAC5-481-1710; 12VAC5-481-1780; 12VAC5-481-1790

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

Discussion: If the applicant intends to perform functions other than the preparation and distribution of radioactive drugs, the applicant may request that an individual other than an ANP perform and/or supervise those functions. This individual, if approved, would be designated on the license as an AU. These other functions may include leak testing of sealed sources or

instrument calibration services for the pharmacy; however, the term 'Authorized User', as used in this document should not be confused with the definition of an "*Authorized User*" contained in **12VAC5-481-10** for medical use.

Note: Licensees must apply for a service license if the applicant wishes to provide services such as leak testing of sealed sources or instrument calibration to their customers or others.

In order to demonstrate adequate training and experience, the proposed AU 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 and measurement instrumentation;
- Biological hazards of exposure to radiation (appropriate to types and forms of radioactive
  material to be used);
- VDH requirements and standards; and
- Hands-on use of radioactive materials commensurate with uses proposed by the applicant.

The length of training and experience listed above will depend upon the type, form, quantity, and proposed use of the radioactive material requested. The proposed AU's training and experience should be sufficient to identify and control the anticipated radiation hazards. The above training may be obtained from formal radiation safety courses consisting of lectures and laboratories presented by academic institutions, commercial radiation safety consulting companies, or appropriate professional organizations. Each hour of training may be counted only once and should be allocated to the most representative topic.

On-the-job training may not count toward the hours listed above unless it was obtained as part of a formal training course. A 'formal' training course is one that incorporates the following elements:

- A detailed description of the content of the course is maintained on file at the sponsoring
  facility or institution and can be made available to the agency upon request;
- Evidence that the sponsoring facility or institution has examined the student's knowledge of
  the course content is maintained on file at the facility or institution and can be made available
  to the agency upon request. This evidence of the student's overall competency in the course material should include a final grade or percentile; and
- A permanent record that the student successfully completed the course is kept at the facility or institution.

The AU must demonstrate training and experience with the type and quantity of material that is to be used at the pharmacy. For example, someone with training and experience only with microcurie quantities of unsealed radioactive material may not be qualified to use or supervise the use of higher activity sealed radioactive sources for instrument calibration. 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:

Item 7 Authorized Users (AU) (Check all that apply)

☐ We will provide the individual's name and identify types, quantities, and proposed uses of licensed material.

AND ONE OF THE FOLLOWING

☐ We will provide a copy of the license (VDH, the NRC or another Agreement State) on which the individual was specified as an AU for the types and quantities and proposed uses of licensed materials.

OR

☐ We will provide a copy of the permit maintained by a broad scope licensee or NRC master material licensee that identifies the individual as an AU for the types, quantities, and proposed uses of licensed materials.

OR

☐ We will provide a description of the training and experience demonstrating that the proposed AU is qualified to use the requested licensed materials. Appendix G in VAREG 'Guidance for Commercial Radiopharmacy' may be helpful in describing the training and experience required.

Item 8: Training for Individuals Working in or Frequenting Restricted Areas

Item 8.1: Occupationally Exposed Workers and Ancillary Personnel

Rule: 12VAC5-481-440; 12VAC5-481-450; 12VAC5-481-480; 12VAC5-481-630; 12VAC5-481-2270; 12VAC5-481-2280

Criteria: Individuals working with radioactive material must receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program. In addition, those individuals who, in the course of employment, are likely to receive in a year a dose in excess of 100 mrem (1 mSv) must be instructed according to **12VAC5-481-2270.**

Discussion: 12VAC5-481-630 requires each licensee to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with of **12VAC5-481 'Virginia Radiation Protection Regulations,' Part IV, 'Standards For Protection Against Radiation'**. Each individual working with radioactive material must be trained in the radiation safety procedures applicable to their job before beginning work with radioactive materials. Licensees should not assume that safety instruction has been adequately covered by prior employment or training. Practical, site-specific training should be provided for all individuals prior to beginning work with, or in the vicinity of, licensed material. Training should also be performed whenever there is a significant change in duties, procedures, rules, or terms of the license.

Each individual that receives greater than 100 mrem (1 mSv) should also receive annual training as specified in **12VAC5-481-2270**. ANPs and others involved in the preparation of radiopharmaceuticals are most likely to receive doses in excess of 100 mrem (1 mSv) in a year; however, potential radiation doses received by all employees must also be evaluated. The evaluation must include consideration of assigned activities during both normal and abnormal situations involving exposure to radiation and/or radioactive material that can reasonably be expected to occur during licensed activities.

If individuals making deliveries of radioactive material at the licensees facility are likely to receive a dose in excess of 100 mrem (1 mSv) in a year from the licensees activities, the licensee is responsible for ensuring that the person has received the training specified in of **12VAC5-481 'Virginia Radiation Protection Regulations', Part X, 'Notices, Instructions and Reports to Workers'**, regardless of whether that person is an employee of the licensee. If the training has been provided by someone else (such as the shipper or another licensee), the licensee does not have to provide training except for instruction in site-specific radiation hazards. This issue is discussed in NRC Generic Letter 95-09, 'Monitoring and Training of Shippers and Carriers of Radioactive Materials,' dated November 3, 1995 which is available from the NRC website at www.nrc.gov.

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. A method should be provided for individuals receiving instructions and training to ask questions. The licensee should determine whether the training succeeded in conveying the desired information and adjust the training program as necessary. The person conducting the training should be a qualified individual (e.g., the RSO, an ANP, AU, or radiation safety professional familiar with the licensee's program).

Licensee personnel who work in the vicinity of, but do not handle radioactive materials (ancillary staff), are not required to have radiation safety training as long as they are not likely to receive 100 mrem (1 mSv) in a year; however, to minimize potential radiation exposure when ancillary staff are working in the vicinity of radioactive material, it is prudent for them to work under the supervision and in the physical presence of an ANP/AU or to be provided some basic radiation safety training. Such ancillary staff should be informed of the nature and location of the radioactive material and the meaning of the radiation symbol, and should be instructed not to handle radioactive materials and to keep away from it as much as their work permits.

Note: Some ancillary staff, although not likely to receive doses over 100 mrem (1 mSv), should receive training to ensure adequate security and control of licensed material. Licensees may provide these individuals with training commensurate with their assignments in the vicinity of the radioactive material to ensure the control and security of the material.

Note: The guidance in **Appendix N** may be used by the applicant to develop a training program.

Response from Applicant:

Item 8.1 Occupationally Exposed Workers And Ancillary Personnel (Check box)

☐ We have developed and will implement and maintain written procedures for a training program for each group of workers including: topics covered; qualifications of the instructors; method of training; method for assessing the success of the training; and the frequency of training and refresher training. (Procedures are Attached)

References: NRC Generic Letter 95-09, 'Monitoring and Training of Shippers and Carriers of Radioactive Materials,' dated November 3, 1995, can be accessed at the NRC website www.nrc.gov under 'Electronic Reading Room', or contact VDH.

Item 8.2: Personnel Involved in Hazardous Materials Package Preparation and Transport

Rule: 12VAC5-481-2980; 49 CFR 172.700; 49 CFR 172.702; 49 CFR 172.704

Criteria: Applicants must train personnel involved in the preparation and transport of hazardous material packages in the applicable DOT regulations.

Discussion: Licensees who prepare packages of radioactive materials or who transport their own packages must provide training to their employees who perform those functions. The training must include:

- General awareness and familiarization training designed to provide familiarity with VDH and DOT requirements, and the ability of the employee to recognize and identify hazardous materials;
- Function-specific training concerning the VDH and DOT requirements that are specifically applicable to the functions the employee performs, (e.g., if the employee's duties require affixing DOT radioactive labels to packages, the employee must receive training in DOT's regulations governing package labeling); and
- Safety training concerning emergency response information, discussed above; measures to protect the employee and other employees from the hazards associated with the hazardous materials to which they may be exposed to in the workplace; and methods of avoiding accidents, such as the proper procedures for handling packages containing hazardous materials.

The training must be provided initially (within 90 days), and every 3 years thereafter. Records of training must be maintained.

Note: The licensee is not responsible for providing DOT-required hazardous materials training to common carriers to which the pharmacy offers radioactive materials packages for transport.

Response from Applicant:

Item 8.2 Personnel Involved In Hazardous Materials Package Preparation And Transport (Check box)
☐ We have developed and will implement and maintain written procedures for training personnel involved in hazardous materials package preparation and transport that meet the requirements in **49 CFR 172.700, 49 CFR 172.702,** and **49 CFR 172.704**, as applicable. (Procedures are Attached)

Item 8.3: Instruction for Supervised Individuals Preparing Radiopharmaceuticals

Rule: 12VAC5-481-440; 12VAC5-481-450; 12VAC5-481-480; 12VAC5-481-1710

Criteria: Individuals who prepare radioactive material for medical use under the supervision of an ANP must be instructed in the preparation of radioactive material for medical use, the principles of radiation safety, and the licensee's procedures for the use of radioactive material; follow the instructions given; and must have their work and records kept to reflect their work periodically reviewed by the supervising ANP.

Discussion: The applicant must instruct supervised individuals in the preparation of radioactive material for medical use and require those individuals to follow their instructions, the written radiation protection program, license conditions, and VDH rules. The supervising ANP must review the work of supervised individuals in the preparation of radioactive material for medical use and the records kept to reflect that work.

An ANP is considered to be supervising the use of radioactive materials when directing personnel in the conduct of operations involving licensed materials. The ANP need not be present at all times during the use of such materials; however, the supervising ANP is responsible for ensuring that personnel under supervision have been properly trained and instructed. This will be addressed by a condition on the radiopharmacy license. The supervising ANP is responsible for the supervision of operations involving the use of radioactive materials.

12VAC5-481 'Virginia Radiation Protection Regulations' does not relieve the licensee from complying with other applicable federal (Food and Drug Administration) and state requirements governing radioactive drugs.

Item 9: Radioactive Material

Part 1: Unsealed and/or Sealed Radioactive Material

Rule: 12VAC5-481-390; 12VAC5-481-440; 12VAC5-481-480; 12VAC5-481-500

Criteria: Applicants must submit information specifying each radionuclide requested; the form; and the maximum activity to be possessed at any one time. For sealed sources, the applicant must also submit the manufacturer and model number of each requested sealed source.

Discussion: Each authorized radioisotope is listed on a VDH license by its element name, form, and the maximum amount the licensee may possess at any one time (maximum possession limit).

The applicant should list each requested radioisotope by its element name and its mass number (e.g., Technetium-99m) in **Item 9**. 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 generally required.

For unsealed radioactive material, it is also necessary to specify whether requested radioisotopes will be handled in volatile or non-volatile form, since additional safety precautions are required when handling and using material in a volatile form. For example, when requesting authorization to possess and distribute Iodine-131, the applicant must specify whether the material will be manipulated at the radiopharmacy in a volatile form (e.g., compounding of Iodine-131 capsules) or received in the form in which it will be distributed (e.g., redistribution of sealed, unopened vials of Iodine-131). Applicants requesting authorization to manipulate volatile radioactive material must describe appropriate facilities and engineering controls in response to **Item 13**, 'Facilities and Equipment', and radiation safety procedures for handling of such material in specific responses to **Item 14.4**, 'Occupational Dosimetry', **Item 14.5**, 'Public Dose', **Item 14.6**, 'Safe Use of Radionuclides and Emergency Procedures', and **Item 14.7**, 'Surveys'.

The anticipated possession limit in becquerels (Bq) or curies (Ci) for each radioisotope should also be specified. Possession limits must include 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 **Item 9, Part 4**.

Applicants will be authorized to possess and use only those sealed sources, such as calibration and reference sources that are specifically approved or registered by the NRC or another Agreement State. A safety evaluation of sealed sources and devices is performed by the NRC or another Agreement State before authorizing a manufacturer (or distributor) to distribute them to specific licensees. Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that the agency can verify that they have been evaluated in a Sealed Source and Device (SSD) Registration Certificate or specifically approved on a license. Before the formalization of the SSD registration process, some older sources or devices may have been specifically approved on a license. Licensees can continue to use those sources and devices specifically listed on their licenses.

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 may want to get a copy of the certificate and review it or discuss it with the manufacturer.

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

A safety evaluation of sealed sources and devices is performed by NRC or another Agreement State before authorizing a manufacturer (or distributor) to distribute them to specific licensees. The safety evaluation is documented in an SSD Registration Certificate. For additional guidance relating to sealed sources and devices, see also NUREG-1556, Vol. 3., "*Applications for Sealed Source and Device Evaluation and Registration*".

Note: If necessary and the manufacturer cannot supply the certificate, SSD Registration Certificates are also available by calling the agency at (804) 864-8150.

The applicant must also request authorization to possess depleted uranium if it will be used for shielding of molybdenum-99/technetium-99m generators. Depleted uranium is frequently used as shielding for generators when the molybdenum-99 activity is greater than 148 gigabecquerels (4 curies). **12VAC5-481-390** exempts depleted uranium from the requirements for a license to the extent that the material is used as a shipping container, such as when molybdenum-

99/technetium-99m generators are in transit from their manufacturer to the pharmacy; however, a specific license or authorization from VDH is needed to possess and use the depleted uranium as a shield during the time that the pharmacy uses or stores the generator at its facility. The applicant must specify the total amount of depleted uranium, in kilograms, that will be needed.

If an applicant requests quantities of licensed material in excess of limits in **12VAC5-481-440 G** (for example, 10 curies of Iodine 131), the applicant must either submit an emergency plan for responding to a release of radioactive materials or perform an evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem (10 mSv) effective dose equivalent or 5 rems (50 mSv) to the thyroid.

Licensees must submit a license amendment and receive VDH authorization before they may make changes in the types, forms, and quantities of materials possessed.

Part 2: Sealed Sources for Calibration and Reference Sources

Rule: 12VAC5-481-440; 12VAC5-481-450; 12VAC5-481-480; 12VAC5-481-500

Criteria: The applicant must specify the uses for sealed sources for reference and calibration.

Discussion: The applicant should describe the intended use of sealed sources. This will normally be for calibration and checks performed only on the applicant's instruments and equipment. Any sources intended for use in a specific instrument calibration device should be identified, along with the manufacturer and model number of the device.

Part 3:Purpose(s) for which Radioactive Material Will Be Used

The distribution of radioactive materials by commercial radiopharmacies is authorized by several distinct rules. The appropriate rule to refer to depends on the nature of the material, the purpose(s) for which it will be used, and to whom it is sent. For example, see the following list:

- Possession and use of radioactive materials (**12VAC5-481-450**)
- Distribution of radiochemicals and radioactive drugs to veterinarians, laboratories and other radiopharmacies. (**12VAC5-481-570**)
- Distribution of radiochemicals to medical use licensees. (**12VAC5-481-570, 12VAC5-481-1900, 12VAC5-481-1920, 12VAC5-481-1950**)
- Preparation and distribute radioactive drugs to medical use licensees. (**12VAC5-481-480, 12VAC5-481-1900, 12VAC5-481-1920, 12VAC5-481-1950**)
- Redistribution of sealed sources to medical use licensees. (**12VAC5-481-480, 12VAC5-481-1830, 12VAC5-481-2010, 12VAC5-481-2020**)
- Redistribution for in vitro, clinical or laboratory testing to general licensees. (**12VAC5-481-430, 12VAC5-481-480**)
- Manufacture of C-14 Urea capsule; radioactive drug for human diagnostic use to persons exempt from licensing. (**12VAC5-481-400**)
- Receive pharmacy originated radioactive waste from customers. (VDH license)
- Perform leak tests and instrument calibration. (VDH license)

Part 4: Financial Assurance and Recordkeeping for Decommissioning

Rule: 12VAC5-481-100; 12VAC5-481-450 C; 12VAC5-481-500; 12VAC5-481-571; 12VAC5-481-1161

Criteria: A licensee authorized to possess radioactive material in excess of the limits specified in **12VAC5-481-450 C** must submit a decommissioning funding plan (DFP) or provide a certification of financial assurance (FA) for decommissioning. Even if a DFP or FA is not required, licensees are required to maintain, in an identified location, decommissioning records related to structures and equipment where radioactive materials are used or stored and related to leaking sources. Pursuant to **12VAC5-481-450 C**, licensees must transfer records important to decommissioning to either of the following:

- The new licensee before licensed activities are transferred or assigned according to **12VAC5-481-500**; or
- 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 commercial radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements, because the vast majority of radioactive materials they possess and redistribute do not have half-lives greater than 120 days and the total inventory of licensed materials with half-lives greater than 120 days do not exceed the thresholds in **12VAC5-481-450 C**.

Applicants requesting more than one radionuclide may determine whether financial assurance for decommissioning is required by calculating, for each radionuclide with a half-life greater than 120 days possessed, the ratio between the activity possessed, in curies, and the radionuclide's threshold activity requiring financial assurance, in curies. If the sum of such ratios for all of the radionuclides possessed exceeds 1 (i.e., 'unity'), then applicants must submit evidence of financial assurance for decommissioning.

The same rule also requires that licensees maintain records important to decommissioning in an identified location. All commercial nuclear pharmacy licensees need to maintain records of structures and equipment where radioactive material was used or stored. As-built drawings with modifications of structures and equipment shown as appropriate fulfill this requirement. If drawings are not available, licensees shall substitute appropriate records (e.g., a sketch of the room or building or a narrative description of the area) concerning the specific areas and locations. If no records exist regarding structures and equipment where radioactive materials were used or stored, licensees shall make all reasonable efforts to create such records based upon historical information (e.g. employee recollections). In addition, if radiopharmacy licensees have experienced unusual occurrences (e.g., incidents that involve spread of contamination, leaking sources), they also need to maintain records about contamination that remains after cleanup or that may have spread to inaccessible areas.

Note: For radiopharmacy licensees whose contamination incidents did not involve radioactive materials with half-lives exceeding 120 days and whose sealed sources have never leaked, acceptable records important to decommissioning are sketches or written descriptions of the specific locations where radioactive material was used or stored.

Note: If financial assurance is required, submit the documentation required under **12VAC5-481-450 C**. 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, contains approved wording for each of the mechanisms authorized by the rule to guarantee or secure funds except for the Statement of Intent for Government licensees. This document is available at the NRC website, www.nrc.gov, or from VDH upon request.

Note: Licensees must transfer records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with **12VAC5-481-500** or to VDH before the license is terminated.

References: To obtain copies of 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, and Policy & Guidance Directive (P&GD) FC 90-2, Revision 1, 'Standard Review Plan for Evaluating Compliance with Decommissioning Requirements' dated April 30, 1991 visit the NRC's website at www.nrc.gov.

Response from Applicant:

Item 9 Radioactive Material (Attach additional pages if necessary)	
Item 9.1 Radioisotope(s)	
Item 9.2 Chemical/physical form of radioisotopes requested.	
Are open containers of potentially volatile materials (Iodine-131) manipulated at this location?	☐ Yes ☐ No If yes, process and engineering controls must be described.
Are sealed sources used at this location?	☐ Yes ☐ No If yes, please fill out Items 9.3 – 9.5, otherwise proceed to Item 9.6
Item 9.3 Sealed source manufacturer or distributor and model number of sealed sources requested.	
Item 9.4 Device manufacturer or distributor and model number of devices requested.	
Is Depleted Uranium used as a shielding material?	☐ Yes ☐ No If yes, specify the total amount (in kilograms) _____
Item 9.5 Maximum possession limit for each radioisotope requested.	
Item 9.6 Proposed use for each radioisotope requested.	

Item 10: Distribution and Redistribution of Licensed Material

Rule: 12VAC5-481-430 G; 12VAC5-481-440; 12VAC5-481-480; 12VAC5-481-570; 12VAC5-481-850; 12VAC5-481-880; 12VAC5-481-2980

Criteria: The applicant must specify the radioactive material it intends to distribute and redistribute.

Discussion: Radiochemicals are those materials that either require further manipulation to be suitable for human use or are not intended for human use. Examples include raw materials received from a non-**12VAC5-481-480** supplier (chemical grade materials). Radioactive drugs are those materials suitable for human use (e.g., monoclonal antibodies and technetium-99m-tagged red blood cells) and radiopharmaceuticals. However, the terms, 'radiopharmaceutical' and 'radioactive drug' will be used interchangeably in this guidance document and reference to one is not meant to exclude the other.

Distribution activities are normally classified as either 'distribution' or 'redistribution'. 'Distribution' applies to those radioactive drugs and radiochemicals initially prepared by the

pharmacy. 'Redistribution' refers to those materials received from another person, authorized pursuant to **12VAC5-481-480**, depending on the product distributed, i.e., *in vitro* kits, other radiopharmaceuticals, or sealed sources for medical use, respectively. The distribution of radioactive materials to other persons requires specific approval from VDH, either by **12VAC5-481 'Virginia Radiation Protection Regulations'** or by a license authorizing the activity. The initial distribution of radioactive drugs for medical use must be prepared by a person licensed pursuant to **12VAC5-481-480**.

The redistribution of *in vitro* kits and sealed sources containing radioactive material for medical use is authorized pursuant to **12VAC5-481-480**, respectively, provided that the materials are not repackaged and the labels are not altered. The *in vitro* kits and sealed sources for medical use intended for redistribution must be initially distributed by a person licensed pursuant to **12VAC5-481-480**, respectively. The transfer of radioactive materials for non-medical use, including radiochemicals, and sealed calibration and reference sources, is authorized pursuant to **12VAC5-481-570**.

All radioactive material listed above shall be distributed only to persons authorized by VDH, the NRC, or another Agreement State license to receive such materials or by a general license **(12VAC5-481-430 G)** to receive *in vitro* test materials.

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

Response from Applicant:

Item 10.1 Radiopharmaceuticals (Check both boxes)

☐ We will confirm that radiopharmaceuticals will be prepared under the supervision of an ANP or will be obtained from a supplier authorized pursuant to **12VAC5-481-480 I**, or under equivalent NRC or another Agreement State requirements;

AND

☐ We will describe all licensed material to be distributed or redistributed.

Item 10.2 Generators (Check all if using generators)

☐ Confirm that the generators will be obtained from a manufacturer licensed pursuant to **12VAC5-481-480 I**, or under equivalent NRC or another Agreement State requirements.

AND

☐ Confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging.

Item 10.3 Redistribution Of Generators (Check all boxes if redistributing generators)

☐ We will submit a description of the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of migration of radioactive fluids out of the generator during transport.

AND

☐ Confirm that the manufacturer's packaging and labeling will not be altered.

AND

☐ Confirm that the generator will not be distributed beyond the expiration date shown on the generator label.

AND

☐ Confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator.

AND

☐ Confirm that only generators used in accordance with the manufacturer's instructions will be redistributed.

Note: Although redistribution of used generators may be authorized by VDH, VDH approval does not relieve the licensee from complying with applicable FDA or other federal or state requirements.

tem 10.4 Redistribution Of Sealed Sources – For Brachytherapy Or Diagnosis (Check all boxes if redistributing sealed sources, for brachytherapy or diagnosis)

☐ Confirm that the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued in pursuant to **12VAC5-481-480 J**, or under equivalent NRC or another Agreement State requirements.

AND

☐ Confirm that the manufacturer's packaging, labeling, and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

Item 10.5 Redistribution Of Calibration And Reference Sealed Sources (Check all boxes if redistributing calibration and reference sealed sources)

☐ Confirm that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a person licensed pursuant to **12VAC5-481-480 J**, or under equivalent NRC or another Agreement State requirements, to initially distribute such sources.

AND

☐ Confirm that the manufacturer's labeling and packaging will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

Item 10.6 Redistribution Of Prepackaged Units For In-Vitro Tests (Check box if redistributing prepackaged units for in-vitro tests)

☐ Confirm that the prepackaged units for in-vitro tests to be redistributed will have been obtained from a manufacturer authorized to distribute the prepackaged units for in-vitro tests in accordance with a specific license issued pursuant to **12VAC5-481-480 G**, or under equivalent license of the NRC or another Agreement State.

Item 10.7 Redistribution To General Licensee (Check all boxes if redistributing to a general licensee)

☐ Confirm that the manufacturer's packaging and labeling of the prepackaged units for in-vitro tests will not be altered in any way.

AND

☐ Confirm that each redistributed prepackaged unit for in-vitro tests will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees.

Item 10.8 Redistribution To Specific License

☐ Confirm that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed prepackaged units for in-vitro test will NOT reference general licenses, exempt quantities, or VDH, NRC, or Agreement State regulations that authorize a general license.

Item 11: Preparation of Radiopharmaceuticals

Rule: 12VAC5-481-450; 12VAC5-481-480

Criteria: The preparation of radiopharmaceuticals for commercial distribution to medical users requires specific authorization.

Discussion: The bulk of radiopharmacy activities involve the preparation of radiopharmaceuticals for commercial distribution to medical users.

Response from Applicant:

Item 11 Preparation Of Radiopharmaceuticals (Check box)

☐ We will attach a document that indicates the types of radiopharmaceuticals preparation activities we intend to perform (e.g. compounding of Iodine-131 capsules, radioiodination, and Technetium-99m kit preparation). (Document is attached)

Item 12: Service Activities

Rule: 12VAC5-481-450; 12VAC5-481-480; 12VAC5-481-500

Criteria: The applicant must specify the radiation protection services it intends to provide to other licensees (e.g., customers), if the service involves the applicant's possession of licensed material (calibration sources and leak test samples).

Discussion: If the applicant intends to provide radiation protection services to customers, the services must be described. Typically these services include instrument calibration and sealed source leak testing. Specific guidance regarding requests to provide service activities is included in NUREG-1556, Volume 18, 'Program-Specific Guidance About Service Provider Licenses' which can be accessed on the NRC's website www.nrc.gov.

Response from Applicant:

Item 12 Service Activities (Check box)

☐ We will submit specific procedures for all radiation protection services that we intend to provide to other licensees (e.g. customers). (Procedures are attached)

Item 13: Facilities and Equipment

Rule: 12VAC5-481-10; 12VAC5-481-440; 12VAC5-481-450 A; 12VAC5-481-480; 12VAC5-481-520; 12VAC5-481-530; 12VAC5-481-630; 12VAC5-481-640; 12VAC5-481-720; 12VAC5-481-730; 12VAC5-481-780; 12VAC5-481-790; 12VAC5-481-850; 12VAC5-481-860; 12VAC5-481-990; 12VAC5-481-2270

Criteria: Radiopharmacies must demonstrate that they are a pharmacy. Facilities and equipment must be adequate to protect health and minimize danger to life or property, minimize the likelihood of contamination, and keep exposures to workers and the public ALARA.

Discussion: Applicants must demonstrate that they are a pharmacy by submitting evidence that they are a licensed as a pharmacy by the Virginia Board of Pharmacy. If the license has not been issued by the Virginia Board of Pharmacy at the time of application, the applicant may provide it at a later date, but prior to license issuance from VDH.

Applicants must provide the agency with documentation demonstrating that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and their employees. The facilities and equipment must also keep exposures to radiation and radioactive materials ALARA and minimize the risks from the uses of the types and quantities of radioactive materials. The applicant should provide clear delineations between its restricted and unrestricted areas through the use of barriers, postings, and worker instructions.

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 cannot 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 are required to be maintained in an identifiable location. For further information, see **Item 9, Part 4**.

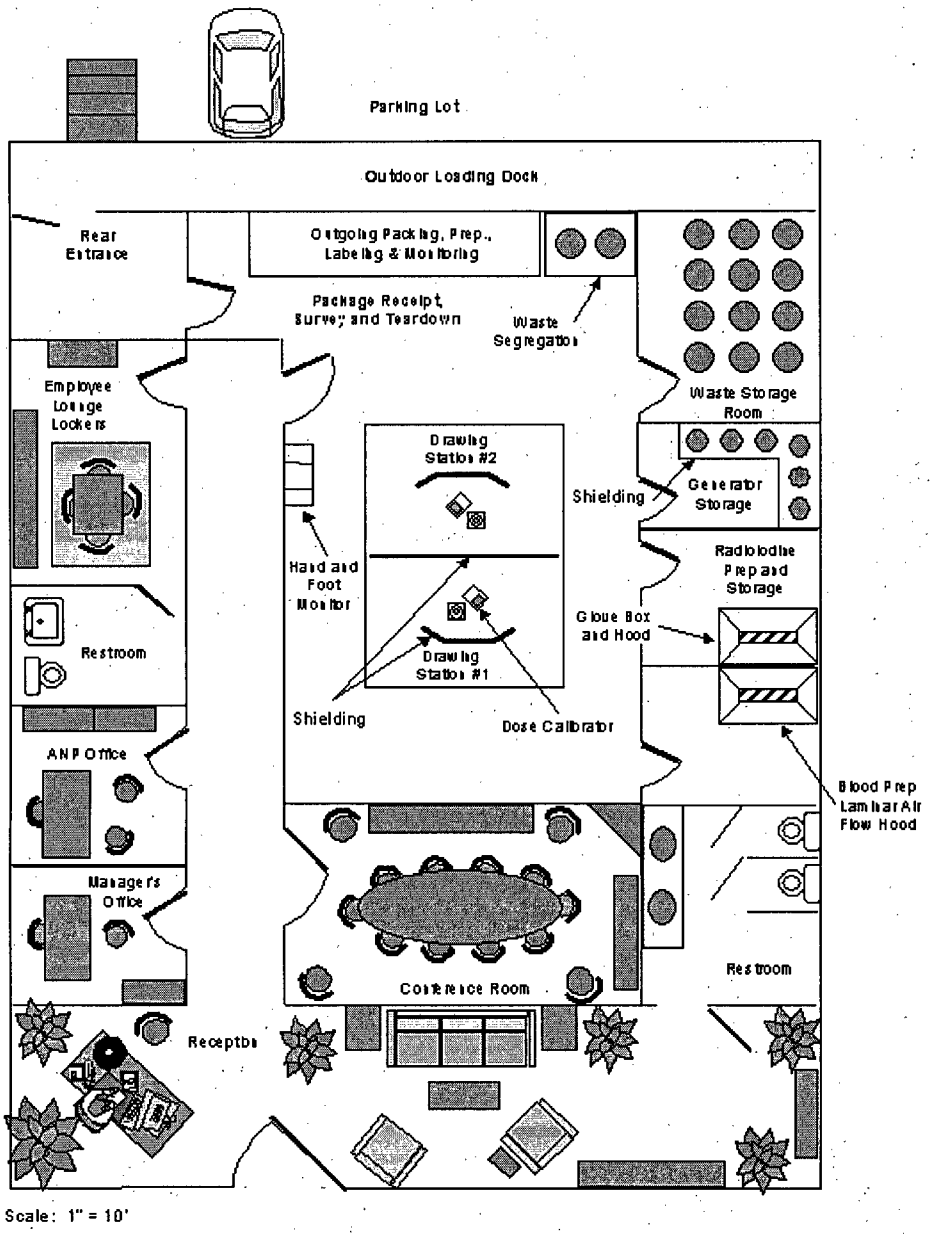


Figure 1. Typical Facility Diagram.

Response from Applicant:

Item 13 Facilities And Equipment (Check boxes and attach diagram.)

☐ We will provide copies of registration or a license from the Virginia Board of Pharmacy as a pharmacy; or evidence that we are operating as a nuclear pharmacy within a state medical institution.

Note: There may be a jurisdiction that does not recognize the practice of commercial radiopharmacy. In these cases, the applicant must submit evidence that it is registered or licensed with the FDA as a drug manufacturer.

AND

☐ We will provide a description of the facilities and equipment to be made available where radioactive material will be used. A diagram should provide be submitted showing the entire facility and identify activities conducted in all contiguous areas surrounding the facility. Diagrams should be drawn to specified scale or dimensions should be indicated. For additional information refer to VAREG 'Guidance for Commercial Radiopharmacy'. (Description is attached)

Item 14: Radiation Safety Program

Item 14.1: Audit Program

Rule: 12VAC5-481-630; 12VAC5-481-990

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

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

Discussion: Appendix I contain a suggested audit program that is specific to commercial radiopharmacies and is acceptable to VDH. All areas indicated in **Appendix I** may not be applicable to every licensee and all items 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 need not be reviewed at the next audit.

Currently, the agency's emphasis during inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of the radiopharmacy to observe whether radiation safety procedures are being followed, etc.

It is essential that once identified, problems be corrected comprehensively and in a timely manner; NRC Information Notice (IN) 96-28, 'Suggested Guidance Relating to Development and Implementation of Corrective Action' provides guidance on this subject. The agency will review the licensee's audit results and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. If violations are identified by the licensee and these steps are taken, the agency can exercise discretion and will normally elect not to cite a violation. The agency's goal is to encourage prompt identification and prompt, comprehensive correction of violations and deficiencies.

Licensees must maintain records of audits and other reviews of program content and implementation for three years from the date of the record. Audit records should contain the following information to be acceptable: date of audit, name of person(s) who conducted the audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up.

Response from Applicant:

Item 14.1 Audit Program
The applicant is not required to, and should not, submit its audit program to VDH for review during the licensing phase. This matter will be examined during an inspection.

References: NRC NUREG – 1600, IN 96-28, and IP 87117 are available electronically at http://www.nrc.gov.

Item 14.2: Radiation Monitoring Instruments

Rule: 12VAC5-481-450; 12VAC5-481-480; 12VAC5-481-630; 12VAC5-481-750; 12VAC5-481-990; 12VAC5-481-1000

Criteria: Licensees must possess radiation monitoring instruments to evaluate possible radiation hazards that may be present. Instruments used for quantitative radiation measurements must be calibrated periodically for the radiation measured.

Discussion: Licensees must possess calibrated radiation detection/measurement instruments to perform, as necessary, the following:

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

For the purposes of this guide, radiation-monitoring instruments are defined as any device used to measure the radiological conditions at a licensed facility. Some of the 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;
- Solid state detectors; and
- Hand and foot contamination monitors.

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.). Radiopharmacies typically use a broad energy range of gamma and beta radiation emitters and need to use radiation detectors appropriate for those energies. Applicants should discuss the types of instruments to be used for each type of survey to be performed and the availability of a sufficient quantity of these instruments at their facility.

Instrument calibrations may be performed by the pharmacy or by another person specifically authorized by VDH, the NRC, or another Agreement State to perform that function. If the pharmacy utilizes the services of another person for instrument calibration, the pharmacy should ensure that person has been authorized by VDH, the NRC, or another Agreement State to perform that activity. **Appendix J** provides information about instrument specifications and model calibration procedures.

Response from Applicant:

Item 14.2 Radiation Monitoring Instruments (Check one box)
☐ We will use equipment that meets the radiation monitoring instrument specifications and implement the survey meter calibration program published in Appendix J of VAREG 'Guidance for Commercial Radiopharmacy'.
OR
☐ We will use equipment that meets the radiation monitoring instrument specifications published in Appendix J of VAREG 'Guidance for Commercial Radiopharmacy', and instruments will be calibrated by other licensees authorized by VDH, the NRC or another Agreement State to perform that service.
OR
☐ We will provide a description of alternative equipment to be used for radiation monitoring and alternative procedures for the calibration of radiation monitoring equipment. (Procedures are attached)

Note: If the applicant intends to provide radiation protection services, including calibration of survey meters, to customers, the applicant must apply for a service license from VDH.

Item 14.3: Material Receipt and Accountability

Rule: 12VAC5-481-100; 12VAC5-481-450; 12VAC5-481-480; 12VAC5-481-490 B; 12VAC5-481-500; 12VAC5-481-570; 12VAC5-481-571; 12VAC5-481-740; 12VAC5-481-840; 12VAC5-481-880; 12VAC5-481-900; 12VAC5-481-910; 12VAC5-481-1090; 12VAC5-481-1840; 12VAC5-481-3100

Criteria: Licensees must ensure the security and accountability of licensed material and must open packages safely.

Discussion: Radioactive materials must be tracked from receipt to disposal in order to ensure accountability, identify when licensed material could be lost, stolen, or misplaced, and ensure that possession limits listed on the license are not exceeded. Licensees exercise control over radioactive 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;
- Maintaining material inventory within license possession limits;
- Transfer of material, including distribution;
- Disposal of material; and
- Use records.

Licensees are required to develop, implement, and maintain written procedures for safely opening packages in accordance with **12VAC5-481-900**. Some packages may require special procedures that take into consideration the type, quantity, or half-life of the nuclide being delivered.

A model procedure for safely opening packages containing licensed materials is included in **Appendix P.**
12VAC5-481-900 states the requirements for monitoring packages containing licensed material. These requirements are described in **Table 2**, below.

Table 2. 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 that Type A	Contamination	As soon as practicable, but not later than 3 hours after receipt of package
Not Labeled	Radioactive Material	None	None
Damaged	Radioactive Material	Contamination Radiation Level	As soon as practicable, but not later than 3 hours after receipt of package.

❖ Assume 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.

12VAC5-481-900 requires that the licensee immediately notify the final delivery carrier and VDH when removable radioactive surface contamination exceeds the limit of 22 disintegrations per minute per square centimeter (dpm/cm^2) averaged over 300 cm^2 (6600 dpm/300 cm^2); or external radiation levels exceed 2.0 mSv/hr (200 mrem/hr) at the surface.

Licensees must secure and control licensed material and should have a means of promptly detecting losses of radioactive material. **12VAC5-481-840** requires licensees to secure radioactive materials from unauthorized removal or access while in storage and to control and maintain constant surveillance over radioactive material that is not in storage.

Licenses will normally contain specific conditions requiring the licensee to perform inventories and leak tests of sealed sources every six months. 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. Sources in storage that are used infrequently may not require leak testing; however, the inventory must still be performed at the specified interval.

With regard to unsealed radioactive 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.

Table 3 list the types and retention times for the records of receipt, use, transfer, and disposal (as waste) of all radioactive material the applicant must maintain. Other records such as transfer records could be linked to radioactive material inventory records.

Table 3. Record Maintenance

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

Material accountability 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 radioactive material (e.g., radionuclide, activity, manufacturer's name and model number, serial number); and
- For radioactive materials disposed of as waste, include the radionuclide, activity, date of disposal, and method of disposal (decay, sewer, etc.).

See **Item 15** on 'Waste Disposal and Transfer' for additional information.

Note: Information about locations where licensed material is used or stored are among the records important to decommissioning and required by **12VAC5-481-450 C**. See **Item 9, Part Four**.

Response from Applicant:

Item 14.3 Material Receipt And Accountability (Check all boxes)

☐ We have developed, and will implement and maintain, written procedures for safely opening packages that meet the requirements in **12VAC5-481-900**.

AND

☐ We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed 6 months.

AND

☐ We have developed, and will implement and maintain written procedures for radioactive material accountability and control to ensure that:

1. License possession limits are not exceeded;
2. Radioactive material in storage is secured from unauthorized access or removal;
3. Radioactive material not in storage is maintained under constant surveillance and control; and
4. Records of receipt, transfer, and disposal of licensed material are maintained.

(Procedures are attached)

Item 14.4: Occupational Dosimetry

Rule: 12VAC5-481-630; 12VAC5-481-640; 12VAC5-481-650; 12VAC5-481-660; 12VAC5-481-670; 12VAC5-481-680; 12VAC5-481-700; 12VAC5-481-710; 12VAC5-481-750; 12VAC5-481-760; 12VAC5-481-990; 12VAC5-481-1000; 12VAC5-481-1020; 12VAC5-481-1040; 12VAC5-481-1100; 12VAC5-481-1110; 12VAC5-481-1130; 12VAC5-481-1140

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 (**12VAC5-481-760**).

Table 4: Occupational Dose Limits for Adults

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

Discussion: The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose (prospective evaluation). When performing the prospective evaluation, only a dose that could be received at the facilities of the applicant or licensee performing the evaluation needs to be considered. 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. For individuals who have received doses at other facilities in the current year, the previous dose need not be considered in the prospective evaluation if monitoring was not required at the other facilities. 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 the prospective evaluation shows that an individual's dose is not likely to exceed 10% of any applicable regulatory limit, the individual is not required to be monitored for radiation exposure and there are no recordkeeping or reporting requirements for doses received by that individual. If the prospective dose evaluation shows that the individual is likely to exceed 10% of an applicable limit, monitoring is required.

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

Internal exposure monitoring is required for:

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

If an individual is likely to receive in 1 year a dose greater than 10% of any applicable limit, monitoring for occupational exposure is required. ANPs and radiopharmacy technologists are generally likely to receive 10% of the limits for occupational dose. Most radiopharmacies provide these employees with whole body and extremity monitors.

Note: Total Effective Dose Equivalent (TEDE) = Deep Dose from External Exposure + Dose from Internally Deposited Radionuclides

When personnel monitoring is needed, most licensees use either film badges or optically stimulated luminescence dosimeters (OSL) that are supplied by a processor holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP). Under **12VAC5-481-750**, 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.

The types and quantities of radioactive material used at most commercial radiopharmacies provide a reasonable possibility for an internal intake by ANPs and radiopharmacy technologists. Uses such as preparing radioiodine capsules from liquid solutions and opening and dispensing from vials containing millicurie quantities of radioiodine and other isotopes require particular caution. Precautionary measures for personnel to follow during iodine capsule preparation should involve the use of a fume hood and glove box or shoulder length gloves (see **Appendix Q** for additional guidance on precautionary measures). To monitor internal exposure from such operations, most pharmacies institute a routine bioassay program to periodically monitor these workers.

A program for performing thyroid uptake bioassay measurements 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 and should address the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue). Thyroid bioassay procedures should also specify the interval between bioassays, action levels, and the actions to be taken at those levels. Generally, thyroid uptake bioassay measurements at radiopharmacies are performed weekly for those workers who routinely handle radioiodine or are in the immediate vicinity when radioiodine is being handled. 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 Doses', dated July 1992, and NRC NUREG - 1400, 'Air Sampling in the Workplace', dated September 1993.

Response from Applicant:

Item 14.4 Occupational Dosimetry (Check all that apply)

☐ We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged at a frequency recommended by the processor.

AND/OR

☐ We will maintain for inspection by the agency, 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 **12VAC5-481-640**.

Note: Some licensees choose to monitor their workers for reasons other than compliance with VDH requirements (e.g., in response to worker requests).

References: National Institute of Standards and Technology (NIST) Publication 810, 'National Voluntary Laboratory Accreditation Program Directory', is published annually and is available electronically at http://ts.nist.gov/nvlap. NIST Publication 810 can be purchased from GPO, whose URL is http://www.gpo.gov. ANSI N322 may be ordered electronically at http://www.ansi.org or by writing to ANSI, 1430 Broadway, New York, NY 10018. NRC Regulatory Guide 8.7, Revision 1, 'Instructions for Recording and Reporting Occupational Radiation Exposure Data', dated June 1992; 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 NRC NUREG - 1400, 'Air Sampling in the Workplace', dated September 1993 can be obtained from the NRC website at www.nrc.gov. Contact VDH Radioactive Materials Program if you have questions.

Item 14.5: Public Dose

Rule:. 12VAC5-481-10; 12VAC5-481-630; 12VAC5-481-720; 12VAC5-481-730; 12VAC5-481-840; 12VAC5-481-1050; 12VAC5-481-1100; 12VAC5-481-1110; 12VAC5-481-3080

Criteria: Licensees must do the following:

- Ensure that radioactive 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) (TEDE) in one year from licensed activities;

- Ensure that air emissions of radioactive material to the environment will not result in exposures to individual members of the public in excess of 0.1 mSv (10 mrem) (TEDE) in one year from those emissions;
- Ensure that the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour, from licensed operations;
- Prevent unauthorized access, removal, or use of radioactive material.

Discussion: Public dose is defined in **12VAC5-481-10** means "*the dose received by a member of the public from exposure to sources of radiation released by the licensee or registrant, or to any other sources of radiation under the control of the licensee or registrant.*" Public dose excludes doses received from background radiation, sanitary sewerage discharges from licensees, and from medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individual's assigned duties. It does not depend on 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 K**.

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

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

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

Licensees should design a monitoring program to ensure compliance with **12VAC5-481-630** and **12VAC5-481-730**. The extent and frequency of monitoring will depend upon each licensee's needs. For additional guidance regarding monitoring of effluents, refer to **Item 14.7**.

During agency inspections, licensees must be able to provide documentation demonstrating, by measurement or calculation, that the TEDE to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit and the dose constraint. See **Appendix K** for examples of methods to demonstrate compliance.

Response from Applicant:

Item 14.5 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 14.6: Safe Use of Radionuclides and Emergency Procedures

Rule: 12VAC5-481-480; 12VAC5-481-630; 12VAC5-481-640; 12VAC5-481-750; 12VAC5-481-760; 12VAC5-481-840; 12VAC5-481-860; 12VAC5-481-870; 12VAC5-481-880; 12VAC5-481-890; 12VAC5-481-1090; 12VAC5-481-1100; 12VAC5-481-1110; 12VAC5-481-2280

Criteria: Licensees are required to do the following:

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

Discussion: Licensees are responsible for the security and safe use of all radioactive material from the time it arrives at their facility until it is used, transferred, and/or disposed. Licensees should develop written procedures to ensure safe use of radioactive 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;
- Safe handling of radioactive materials;
- Recording requirements;
- Reporting requirements; and
- Responsibilities.

These procedures should include policies for:

- Frequency of personnel monitoring;
- Performing molybdenum-99 breakthrough measurements on each elution from a generator;
- Use of appropriate shielding;
- Frequent glove changes to minimize exposure to the individual and to avoid spread of contamination in the laboratory; and
- Special procedures for higher risk activities, such as use of radioiodine.

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

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

Emergency Procedures

Accidents and emergencies can happen during any operation with radioisotopes, including their receipt, 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 radioactive material, and fires involving radioactive material can adversely affect the safety of personnel and members of the public. Applicants should therefore develop and implement procedures to minimize, to the extent practical, the potential impact of these incidents on personnel, members of the public, and the environment.

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 staff and the radiation safety officer. In addition, the licensee should develop procedures for routine contacts with its local fire department to inform them of its operations and identify locations of radioactive materials and elevated radiation levels in the event of their response to a fire. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, licensee staff should have a clear understanding of their limitations in an emergency with step-by-step instructions and clear direction of whom to contact. The licensee should establish clear delineation's between minor contamination events, minor spills, and major spills and events.

Emergency spill response materials should be strategically placed in well-marked locations for use by all trained staff. All equipment should be periodically inspected for proper operation and replenished as necessary. **Appendix Q** includes model emergency procedures. Applicants may adopt these procedures or develop their own incorporating the safety features included in these model procedures.

Certain incidents and emergencies require notification of VDH. **Appendix T** provides a listing of major VDH reporting and notification requirements relevant to commercial radiopharmacies.

Response from Applicant:

Item 14.6 Safe Use Of Radionuclidies And Emergency Procedures (Check box)

☐ We will develop, implement, and maintain safe use of radionuclides and emergency procedures that meets the criteria in the section titled 'Safe Use of Radionuclides and Emergency Procedures' in VAREG 'Guidance for Commercial Radiopharmacy'. (Procedures are Attached)

Item 14.7: Surveys

Rule: 12VAC5-481-630; 12VAC5-481-740; 12VAC5-481-750; 12VAC5-481-1000

Criteria: Licensees are required to make surveys of potential radiological hazards in their workplace. Records of survey 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), 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 the radiological conditions. In order to meet regulatory requirements for surveying, measurements of radioactivity should be understood in terms of their properties (i.e., alpha, beta, gamma) and compared to the appropriate limits.

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 rules. 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 radiopharmaceuticals are handled or processed in unsealed form and where operations could expose workers to the inhalation of 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 returns from customers) and departing (e.g., prepared radiopharmaceuticals for shipment to customers).

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 from external and internal exposure. Also, the frequency of the survey depends on the type of survey, such as those listed above. **Appendix R** contains a procedure for radiation survey frequencies.

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 is an important aspect of any radiation safety program.

12VAC5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation' does not specify limits for surface contamination, but it does specify dose limits for unrestricted areas (2 millirem in any one hour) and posting requirements (5 millirem in any one-hour for "*Radiation Areas*"). Each applicant should propose and justify their removable surface contamination and radiation level action limits that will require action to (1) reduce the contamination or radiation level; or (2) institute additional restrictions on access to the area. See **Table 7** located in **Appendix R** for guidance on surface contamination limits acceptable to VDH.

Undetected Contamination and Loss of Control of Radioactive Material

Due to the large quantities of radioactive material in liquid form often handled by radiopharmacy personnel, there can be a greater potential for radioactive material contamination. Radiation surveys, if properly conducted as outlined in this section, will normally detect contamination before it leaves the licensee's restricted area (e.g., radiopharmceutical preparation and packaging areas). If detected within the restricted area during or shortly following radiopharmaceutical preparation, the licensee can normally complete standard decontamination activities to mitigate the spread of the contamination outside the restricted area.

There have been several instances involving licensees, including radiopharmacies, in which contamination has not been detected (usually due to no survey being done, or else an inadequate survey being performed) and which is inadvertently removed from the restricted area. Typically the contamination has been deposited on an outgoing package containing radioactive material, the skin or clothing of a licensee employee leaving the facility, or both. Once the contamination leaves the licensee's restricted area, control of the radioactive material is lost. At this point the contamination has a high probability of reaching public locations outside the radiopharmacy including one or more of its customers (e.g., a hospital). Contamination incidents such as this can create public health, regulatory, and public relations problems for licensees. In virtually all cases, the events could have been avoided if licensee personnel had performed an adequate radiation survey to detect the contamination before leaving the restricted area.

Response from Applicant:

Item 14.7 Surveys (Check one box)

☐ We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix R of VAREG 'Guidance for Commercial Radiopharmacy'.

OR

☐ We will develop, implement, and maintain written procedures for a survey program that specifies the performance of radiation and contamination level surveys in restricted and unrestricted areas, personnel contamination monitoring, action levels, and the frequencies and records maintenance of those surveys and monitoring that meet the requirements in **12VAC5-481-100**, **12VAC5-481-750,** and **12VAC5-481-1000**.

References: NRC Information Notice 98-18, 'Recent Contamination Incidences Resulting From Failure to Perform Adequate Surveys,' dated May 13, 1998 can be found on the NRC's website www.nrc.gov. Contact VDH Radioactive Materials Program with questions.

Item 14.8: Dose Calibrator and Other Dosage Measuring Equipment

Rule: 12VAC5-481-480; 12VAC5-481-750; 12VAC5-481-880; 12VAC5-481-1800; 12VAC5-481-1820; 12VAC5-481-1850

Criteria: Commercial radiopharmacy licensees must possess and use instrumentation capable of accurately measuring the radioactivity in radioactive drugs.

Discussion: Due to the potential for radiopharmacy errors to adversely affect their customers (medical facilities) and their customers' patients, each dosage of a radioactive drug must be measured prior to transfer to provide high confidence that the correct amount of the radioactive drug is transferred in accordance with the customer's request.

The applicant must have procedures for the use of the instrumentation, including the measurement, by direct measurement or by combination of measurement and calculation, of the

amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to their transfer for commercial distribution.

These procedures must ensure that the dose calibrator, or other dose measurement system, functions properly. This is accomplished by performing periodic checks and tests prior to first use, followed by checks at specified intervals, and following repairs that could affect system performance. Equipment used to measure dosages that emit gamma, alpha, or beta radiation must be calibrated for the applicable radionuclide being measured. Currently, no alpha-emitting nuclides are used in unsealed form in medicine; therefore, guidance is not provided in this document on the measurement of these radionuclides. For photon-emitters, activity measurement is a fairly straightforward determination; however, for beta-emitters, a correction factor is often necessary to accurately determine the activity. There are inherent technical difficulties to overcome in the determination and application of beta-correction factors. These difficulties include dependence on geometry, lack of an industry standard for materials used in the manufacture of both vials and syringes, and lack of a National Institute of Standards and Technology (NIST) traceable standard for all radionuclides currently in use. If radiopharmacies intend to initially distribute (i.e., measure, prepare, and label) beta-emitting radionuclides, the applicant must provide the calculation to demonstrate its ability to accurately dispense such materials. If the applicant intends to use beta-correction factors supplied by the instrument manufacturer, or other entity, it should include a means for ensuring the accuracy of the supplied factor. If radiopharmacy applicants intend to only redistribute beta-emitting radionuclides that have been previously prepared and distributed by other persons licensed pursuant to **12VAC5-481-480** then the correction factor calculation is not required.

Licensees must assay patient dosages in the same type of vial and geometry as used to determine the correct dose calibrator settings. The use of different vials or syringes may result in measurement errors, for example, due to the variation of bremstrahlung 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 bremstrahlung, followed by a high-atomic-numbered material thick enough to attenuate the bremstrahlung intensity.

For each dose measurement system, specific periodic tests must be performed, as appropriate, to the system to ensure correct operation. Typically, all systems must be checked each day of use for constancy to ensure continued proper operation of the system. In addition, other appropriate tests may include accuracy (for the range of energies to be measured), linearity (for the range of activities to be measured), and geometry dependence (for the range of volumes and product containers).

The applicant should ensure that it possesses a sufficient number of such instruments to allow for periods when instruments are out of service for repair and calibration.

Appendix O contains a model procedure for dose calibrator testing.

Note: If the applicant intends to provide radiation protection services, including calibration of dose calibrators, to customers, the applicant must apply for a service license from VDH.

Response from Applicant:

Item 14.8 Dose Calibrator And Other Dosage Measuring Equipment (Check all that apply)
☐ We will describe the types of systems (measurement or combination of measurement and calculation) that we intend to use for the measurement of alpha-, beta-, and photon-emitting radioactive drugs.
AND
☐ We will develop, implement, and maintain a written procedure for the performance of dose measurement system checks and tests that meet the requirements in **12VAC5-481-480 I**. (Procedures are attached)
AND EITHER
☐ We will provide, if applicable, a sample calculation for determining beta-correction factors for dose calibrators with ionization chambers.
OR
☐ We will include, if applicable, a means for ensuring the accuracy of beta-correction factors supplied by the instrument manufacturer or other entity.

Item 14.9: Radioactive Drug Labeling for Distribution

Rule: 12VAC5-481-470; 12VAC5-481-850; 12VAC5-481-880; 12VAC5-481-890

Criteria: The labels affixed to radioactive drugs for distribution must have the required color, symbol, and wording.

Discussion: The licensee must label each 'transport radiation shield' to show the radiation symbol as described in **12VAC5-481-880**. The label must also include the words "*CAUTION, RADIOACTIVE MATERIAL*" or "*DANGER, RADIOACTIVE MATERIAL*", the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specified date and time. The phrase 'transport radiation shield' refers to the primary shield for the radioactive drug, which may include the syringe, vial, or syringe or vial shield. The 'transport radiation shield' should be constructed of material appropriate for the isotope to be transferred for commercial distribution. The 'transport radiation shield' does not refer to the outer suitcase, packaging, or other carrying device, even though that barrier may provide some radiation shielding.

The licensee must label each syringe, vial, or other container (e.g., generator or ampule) used to hold radioactive drugs to be transferred for commercial distribution to show the radiation symbol, as described in **12VAC5-481-880**. The label must include the words "*CAUTION, RADIOACTIVE MATERIAL*" or "*DANGER, RADIOACTIVE MATERIAL*", and an identifier that ensures the syringe, vial, or other container can be correlated with the information on the 'transport radiation shield' label. The identifier must provide a correlation between the syringe, vial, or other container and the information on the label of its 'transport radiation shield'. Identifiers may include the prescription number, the name of the radioactive drug or its abbreviation, the name of the patient, or the clinical procedure.

Response from Applicant:

Item 14.9 Radioactive Drug Labeling For Distribution (Check both boxes)
☐ We will describe all labels, indicating the colors to be used, that will accompany the products and describe where each label is placed (e.g. on the 'transport radiation shield' or the container used to hold the radioactive drug). (Description is attached)
AND
☐ We agree to affix the required labels to all 'transport radiation shields' and each container used to hold the radioactive drugs.

Item 14.10: Radioactive Drug Shielding for Distribution

Rule: 12VAC5-481-480; 12VAC5-481-630; 12VAC5-481-640

Criteria: The shielding provided for each radioactive drug to be distributed must be adequate for safe handling and storage by the pharmacy's customers to maintain occupational exposures ALARA.

Discussion: The applicant must provide appropriate 'transport radiation shields' for the primary container of each radioactive drug that it intends to distribute. The shielding must be adequate for the types and activities of radioactive materials that the applicant intends to distribute. Typically, 'transport radiation shields' used by radiopharmacies have included two-piece, shielded syringe and vial containers (or 'pigs'). Pharmacies have used lead and tungsten shields for gamma-emitting materials and plexiglass inserts for beta-emitters.

As general guidelines, 'transport radiation shields' for Technetium-99m products have ensured surface radiation levels of not more than 0.03 milliSievert per hour (mSv/hr) (3 mrem/hr), due to the ease of shielding the low energy gamma emitted. For Iodine-131, surface dose rates on 'transport radiation shields' have been approved up to 0.5 mSv/hr (50 mrem/hr) for diagnostic dosages and up to 1.5 mSv/hr (150 mrem/hr) for therapeutic dosages. The applicant should select appropriate shielding materials and dimensions to not only ensure that occupational doses are ALARA, but also that the 'transport radiation shield' can be easily handled.

Response from Applicant:

Item 14.10 Radioactive Drug Shielding For Distribution (Check box)
☐ For each drug to be distributed, we will (except for products intended for redistribution without manipulation and in the manufacturer's original shipping package): • Indicate the radionuclide and the maximum activity for each type of container (e.g. vial, syringe); • Describe the type and thickness of the 'transport radiation shield' provided for each type of container; and • Indicate the maximum radiation level to be expected at the surface of each 'transport radiation shield' when the radioactive drug container is filled with the maximum activity.
Note: It is not acceptable to state that the applicant will comply with DOT regulations. The dose rate limits that DOT imposes apply to the surface of the package, not the surface of the 'transport radiation shield'.

Item 14.11: Leak Test

Rule: 12VAC5-481-740; 12VAC5-481-750; 12VAC5-481-1010; 12VAC5-481-1150

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

Discussion: A licensee will be required to perform leak tests at intervals not to exceed six months unless otherwise approved by VDH, the NRC, or another Agreement State and it is documented in the SSD Registration Sheet. The measurement of the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 becquerels (0.005 microcurie) of radioactivity.

Commercial radiopharmacies may have their sealed sources leak tested by an individual licensed by VDH, the NRC, or another Agreement State to perform leak testing or radiopharmacies may perform leak testing of their own sealed sources. **Appendix L** contains a procedure for performance of leak testing and sample analysis. If the radiopharmacy has its leak testing performed by a licensed leak test provider, the radiopharmacy is expected to take the leak test samples according to the sealed source manufacturer's and the leak test provider's kit instructions and return it to the provider 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.

Response from Applicant:

Item 14.11 Leak Test (Check one box)

☐ 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 supplier's instructions.

License number of organization authorized to perform or analyze leak test (Specify whether VDH, NRC, or another Agreement State):

Organization Name: _____ License Number _____
Issuing Agency _____

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 another Agreement State.

OR

☐ We will perform our own leak testing and sample analysis. We will follow the procedures in Appendix L of VAREG 'Guidance for Commercial Radiopharmacy'.

OR

☐ We will submit alternative procedures. (Procedures are attached)

Note: If the applicant intends to provide radiation protection services, including leak testing, to customers, the applicant must apply for a service license from VDH.

Item 14.12: Transportation

Rule: 12VAC5-481-100; 12VAC5-481-480; 12VAC5-481-570; 12VAC5-481-571; 12VAC5-481-630; 12VAC5-481-840; 12VAC5-481-2980; 12VAC5-481-2990; 12VAC5-481-3000; 12VAC5-481-3010; 12VAC5-481-3020; 12VAC5-481-3030; 12VAC5-481-3070; 12VAC5-481-3080; 12VAC5-481-3091; 12VAC5-481-3100; 12VAC5-481-3110; 12VAC5-481-3130; 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 those materials to ensure compliance with VDH and U.S. Department of Transportation (DOT) regulations.

Discussion: The agency inspects and enforces DOT's regulations governing the transport of radioactive materials by VDH's licensees.

The types and quantities of radioactive materials shipped by commercial radiopharmacy licensees will nearly always meet the criteria for shipment in a "*Type A*" package, as defined by the DOT. The requirements for these packages include the provisions for shipping papers, packaging design standards, package marking and labeling, and radiation and contamination level limits. For radiopharmacies who transport their own packages, the packages must be blocked and braced, and shipping papers must be used and located properly in the driver's compartment.

Packaging used by commercial radiopharmacies typically includes military ammunition boxes, 'briefcases', and cardboard/fiberboard boxes. These packages will normally meet the criteria for "*Type A*" quantities, which must meet specified performance standards to demonstrate that they will maintain the integrity of containment and shielding under normal conditions of transport. Such packages will normally withstand minor accident situations and rough handling conditions. The testing criteria for Type A packages are listed in **49 CFR 173.465**. Before offering a Type A package for shipment, the shipper is responsible for ensuring that the package has been tested to meet the criteria for the contents and the configuration to be shipped and maintaining a certificate of testing. Shippers are not required to personally test the packages, but must ensure that the testing was performed before use and maintain a record of the testing.

DOT regulations also require that individuals who perform functions related to the packaging and shipment of radioactive material packages receive training specific to those functions. The training must include a general awareness of DOT requirements, function-specific training for the individuals' duties, and safety training. DOT also specifies the frequency of the training and a record retention requirement for training (see **Item 8**).

An outline of DOT and VDH requirements generally relevant to commercial radiopharmacy operations is included for applicant and licensee reference in **Appendix M**.

References: 'A Review of Department of Transportation Regulations for Transportation of Radioactive Materials', can be obtained be calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4425. The Memorandum of Understanding with DOT on the Transportation of Radioactive Material, signed June 6, 1979, is available from NRC.

Item 14.13: Minimization of Contamination

Rule: 12VAC5-481-450 A; 12VAC5-481-630; 12VAC5-481-510; 12VAC5-481-1161

Criteria: Applicants for new licenses must describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the 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. In the case of commercial radiopharmacy applicants, these issues usually do not need to be addressed as a separate item, as they are included in responses to other items of the application.

The bulk of unsealed radioactive material utilized by radiopharmacies have short half-lives (under 120 days). These radionuclides do not pose a source of long-term contamination. Additionally, nearly all radioactive waste generated by radiopharmacies is stored for decay rather than transferred to a radioactive waste disposal facility.

The licensee may possess and redistribute sealed sources that contain radionuclides with long half-lives. These sealed sources have been approved by NRC or another Agreement State and, if used according to the respective SSD Registration Certificate, usually pose little risk of contamination. Leak tests performed at the frequency 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.

Item 15: Waste Disposal and Transfer

Item 15.1: Waste Management

Rule: 12VAC5-481-100; 12VAC5-481-450; 12VAC5-481-480; 12VAC5-481-570; 12VAC5-481-571; 12VAC5-481-630; 12VAC5-481-720; 12VAC5-481-750; 12VAC5-481-880; 12VAC5-481-900; 12VAC5-481-910; 12VAC5-481-920; 12VAC5-481-930; 12VAC5-481-940; 12VAC5-481-950; 12VAC5-481-960; 12VAC5-481-970; 12VAC5-481-971; 12VAC5-481-1000; 12VAC5-481-1060; 12VAC5-481-1100; 12VAC5-481-1890; 12VAC5-481-2571; 12VAC5-481-2980; 12VAC5-481-3690

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, and 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 to do so by VDH. Commercial radiopharmacies may request to receive certain radioactive waste returned from their customers. For guidance on receiving radioactive waste from customers, refer to the section titled, 'Returned Wastes from Customers'.

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 commercial radiopharmacy licensees to manage radioactive waste generated at their facilities by one or more of the following methods:

- Decay-in-Storage (DIS);
- Transfer to an authorized recipient; and
- Release into sanitary sewerage.

Licensees may choose any one or more of these methods to dispose of their radioactive waste. Most commercial radiopharmacies dispose of radioactive waste by decay-in-storage because the majority of radioactive materials used by these facilities have short half-lives.

Applicant's programs for management and disposal of radioactive waste 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. **12VAC5-481 'Virginia Radiation Protection Regulations'** requires licensees to maintain all appropriate records of disposal of radioactive waste.

Disposal by Decay-in-Storage (DIS)

VDH permits radioactive materials with half-lives of less than or equal to 120 days to be disposed by DIS. The minimum holding period for decay is ten half-lives of the longest-lived radioisotope in the waste. Applicants should assure that adequate space and facilities are available for the storage of such waste. Procedures for management of waste by DIS should include methods of segregation, surveys prior to disposal, and maintenance of records of disposal.

Licensees can minimize the need for storage space, if radioactive waste is segregated according to physical half-life. Segregation of waste is accomplished by depositing radioisotopes of shorter physical half-lives in containers separate from those used to store radioactive waste with longer physical half-lives. Radioactive waste with shorter half-lives will take less time to decay and thus may be disposed in shorter periods of time, freeing storage space.

Used syringes/needles and vials returned from pharmacy customers (medical facilities) are considered both biohazardous and radioactive waste since these items may be contaminated with the customer's patients' blood or other body fluids. Following completion of decay-in-storage, such waste may be disposed of as biohazardous waste (medical waste) if radiation surveys (performed in a low background area and without any interposed shielding) of the waste at the end of the holding period indicate that radiation levels are indistinguishable from background.

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

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

Other pharmacy radioactive waste that has not been returned from customers and has not otherwise come into contact with blood or body fluids should not have a biohazardous component. Following completion of DIS and provided it has been stored separate from radioactive, biohazardous waste and contains no other hazardous components (e.g. needles, hazardous chemicals), such waste may require disposal 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 final 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.

Records of DIS 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, results of final survey before disposal as ordinary trash and results of the background survey, identification of the instrument used to perform the survey and the signature or initials of the individual performing the survey.

Transfer to an Authorized Recipient

Licensees may transfer radioactive waste to an authorized recipient for disposal. Most commercial radiopharmacies only dispose of radioactive wastes with half-lives greater than 120 days to authorized recipients (e.g., low-level radioactive waste disposal facilities). Since radiopharmacy licensees typically possess small quantities of these materials, the volume of materials disposed in this manner would also be minimal, if any. Currently, radiopharmacies use this system for waste disposal infrequently; therefore, detailed guidance is not provided in this document on the specific requirements related to the transfer of wastes to authorized recipients for disposal.

Release Into Sanitary Sewerage

Licensees may dispose of radioactive waste by release into sanitary sewerage if each of the following conditions are 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 **12VAC5-481-3690, Table III**;
- If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit in **12VAC5-481-3690, Table III,** cannot exceed unity; and
- Total quantity of licensed material released into the sanitary sewerage system in a year does not exceed the limits specified in **12VAC5-481-930**.

Licensees are responsible for demonstrating that licensed materials discharged into the sewerage system are, indeed, readily dispersible in water. NRC IN 94-07, 'Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20', dated January 1994, provides the criteria for evaluating solubility of liquid waste.

Applicants shall develop and implement procedures to ensure that all releases of radioactive waste into the sanitary sewerage, if any, meet the criteria stated in **12VAC5-481-930**. Licensees are required to maintain accurate records of all releases of radioactive material into the sanitary sewer.

Response from Applicant:

Item 15.1 Waste Management (Check box)
☐ We will develop, implement, and maintain procedures for waste collection, storage, and disposal by any of the authorized methods described in the section titled 'Waste Management' of VAREG 'Guidance for Commercial Radiopharmacy'. We will contact VDH for guidance to obtain approval of any method(s) of waste disposal other than those discussed in the section titled 'Waste Management' of VAREG 'Guidance for Commercial Radiopharmacy'. (Procedures are attached)

References: NRC Policy and Guidance Directive PG 94-05, 'Updated Guidance on Decay-In-Storage', dated October 1994; NRC Information Notice 94-07, 'Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20', dated January 1994; and NRC Information Notice 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 can be accessed from the NRC's website at http://www.nrc.gov. Contact VDH Radioactive Materials Program with questions.

Item 15.2: Returned Wastes from Customers

Rule: 12VAC5-481-450; 12VAC5-481-480; 12VAC5-481-570; 12VAC5-481-910; 12VAC5-481-2980

Criteria: Commercial radiopharmacies may receive radioactive waste from customers. This radioactive waste is limited to items that originated at the radiopharmacy and that contained (or contain) radioactive material delivered for customer use (e.g., pharmacy supplied syringes and vials and their contents).

Discussion: Commercial radiopharmacy licenses contain a license condition that permits radioactive waste, consisting of pharmacy supplied items, to be received from their customers. The customer may return, and the radiopharmacy may accept for disposal, only items originating at the radiopharmacy that contained or contain radioactive material. This is limited to pharmacy-supplied syringes and vials and their contents. It is not acceptable for customers to return items originating at their facilities that are contaminated with radioactive material supplied by the pharmacy (e.g., gloves, absorbent material, IV tubing, patient contaminated items). If an applicant wishes a broader authorization for radioactive waste retrieval, the applicant must apply for a separate license as a radioactive waste broker under the general provisions of **12VAC5-481-450** and **12VAC5-481-910.**

Radiopharmacy customers, who act as the shipper for returned materials, should be supplied with detailed written instructions on how to properly prepare and package radioactive waste for return to the radiopharmacy. These instructions should clearly indicate that only items that contained or contain radioactive materials supplied by the radiopharmacy may be returned. In addition, these instructions should be adequate to ensure that customers comply with Department of Transportation (DOT) regulations and VDH rule for the packaging and transport of radioactive materials and for the radiation safety of drivers/couriers. Since customers may return unused syringes and vials, which may contain significant quantities of radioactive material, the radiopharmacy should also include in their instructions methods for determining that the activities of radioisotopes returned to the pharmacy are "*Limited Quantities*", or otherwise ensure that customers prepare and offer packages for transport that meet VDH and DOT requirements if the packages contain greater than limited quantities of radioactive material. The radiopharmacy should also have written instructions for pharmacy staff to address pick-up, receipt, and disposal of the returnable radioactive waste. **Appendix S** contains a procedure for return of pharmacy radioactive wastes from customers.

If the pharmacy chooses to take the responsibility to act as the shipper for returned materials, the pharmacy must ensure that its customer follows DOT regulations and VDH rule for the packaging and transport of radioactive materials and for the radiation safety of drivers/couriers in the return process.

Response from Applicant:

Item 15.2 Returned Waste From Customers (Check one box)
☐ We will follow the procedures for returned waste from customers in Appendix S of VAREG 'Guidance for Commercial Radiopharmacy'.
OR
☐ We will develop, implement and maintain procedures for returned waste from customers, that will meet the criteria in the section titled 'Returned Waste from Customers' in VAREG 'Guidance for Commercial Radiopharmacy'. (Procedures are attached)

Note: Retrieval, receipt, and disposal of pharmacy supplied syringes and vials from customers is authorized via a license condition.

Item 16: License Fees

On VDH form, 'Application for A Radioactive Material License for Commercial Radiopharmacies' (**Appendix A**), enter the fee category and the amount. Enclose fee with the application.

Response from Applicant:

Item 16 License Fees (12VAC5-490.)	
Category:	License fee enclosed ☐ Yes ☐ No Amount Enclosed_____

Item 17: Certification

Individuals acting in a private capacity are required to sign and date VDH form, 'Application for Radioactive Material License for Commercial Radiopharmacies' (**Appendix A**). Otherwise, senior representatives of the corporation or legal entity filing the application should sign and date VDH form, 'Application for Radioactive Material License for Commercial Radiopharmacies' (**Appendix A**).

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. VDH will return all unsigned applications for proper signature.

Note:

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

Response from Applicant:

CERTIFICATION (To be signed by an individual authorized to make binding commitments on behalf of the applicant.)	
Item 17 I hereby certify that this application was prepared in conformance with **12VAC5-481 '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 A:

VDH Form,
'Application for a Radioactive Material License for Commercial Radiopharmacies'

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

APPLICATION FOR A RADIOACTIVE MATERIAL LICENSE FOR A COMMERICAL RADIOPHARMACY

The Virginia Department of Health 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 Commercial Radiopharmacy." Use supplementary sheets where necessary. Retain one copy and submit original of the entire application to the Virginia Department of Health, Radioactive Materials Program, 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):
( ) - .x	( ) - x

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

RADIATION SAFETY OFFICER

Item 5 Radiation Safety Officer (RSO) (Check all that apply and attach evidence of training and experience)

NAME TELEPHONE NUMBER ( ) - x

(Include area code)

☐ We will submit an organizational chart describing the management structure, reporting paths, and the flow of authority between executive management and the RSO.

AND EITHER

☐ A copy of the license (VDH, the NRC or an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO, an Authorized Nuclear Pharmacist, or an Authorized User.

OR

☐ A description of the training and experience demonstrating that the proposed RSO is qualified by training and experience as applicable to commercial nuclear pharmacies. Appendix G in VAREG 'Guidance for Commercial Radiopharmacy' should be used in documenting and determining required training and experience.

AUTHORIZED NUCLEAR PHARMACIST

Item 6 Authorized Nuclear Pharmacist (ANP) (Check all that apply and attach evidence of training and experience)

☐ We will provide a copy of the State pharmacy licensure for each pharmacist.

AND ONE OF THE FOLLOWING

☐ We will provide a copy of the license (VDH, the NRC or an Agreement State) on which the individual was specifically named as an ANP.

OR

☐ We will provide a copy of the permit maintained by a broad scope licensee or NRC master material licensee.

OR

☐ We will provide a copy of the certification(s) for the radiopharmacy board(s), and e will provide a written certification, signed by a preceptor ANP, that the training and experience as specified in **12VAC5-481-1770** has been completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

OR

☐ We will provide a description of the training and experience demonstrating that the proposed ANP is qualified by training and experience, and we will provide a written certification, signed by a preceptor ANP, that the training and experience as specified in **12VAC5-481-1770** has been completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

AUTHORIZED USERS

Item 7 Authorized Users (AU) (Check all that apply)

☐ We will provide the individual's name and identify types, quantities, and proposed uses of licensed material.

AND ONE OF THE FOLLOWING

☐ We will provide a copy of the license (VDH, the NRC or another Agreement State) on which the individual was specified as an AU for the types and quantities and proposed uses of licensed materials.

OR

☐ We will provide a copy of the permit maintained by a broad scope licensee or NRC master material licensee that identifies the individual as an AU for the types, quantities, and proposed uses of licensed materials.

OR

☐ We will provide a description of the training and experience demonstrating that the proposed AU is qualified to use the requested licensed materials. Appendix G in VAREG 'Guidance for Commercial Radiopharmacy' may be helpful in describing the training and experience required.

TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Item 8.1 Occupationally Exposed Workers And Ancillary Personnel (Check box if applicable)

☐ We have developed and will implement and maintain written procedures for a training program for each group of workers, including: topics covered; qualifications of the instructors; method of training; method for assessing the success of the training; and the frequency of training and refresher training. (Procedures are attached)

Item 8.2 Personnel Involved In Hazardous Materials Package Preparation And Transport (Check box if applicable)

☐ We have developed and will implement and maintain written procedures for training personnel involved in hazardous materials package preparation and transport that meet the requirements in 49 CFR 172.700, 49 CFR 172.702 AND 49 CFR 172.704, as applicable. (Procedures are attached)

RADIOACTIVE MATERIALS

Item 9 Radioactive Material (Attach additional pages if necessary)

Item 9.1 Radioisotope(s)

Item 9.2 Chemical/Physical Form of radioisotopes requested.

Are open containers of potentially volatile materials (Iodine-131) manipulated at this location?	☐ Yes ☐ No If yes, process and engineering controls must be described.
Are sealed sources used at this location?	☐ Yes ☐ No ***If yes, please fill out Items 9.3 – 9.5, otherwise proceed to Item 9.6***

Item 9.3 Sealed Source Manufacturer or Distributor and Model Number of sealed sources requested.

Item 9.4 Device Manufacturer or Distributor and Model Number of devices requested.

Is Depleted Uranium used as a shielding material?	☐ Yes ☐ No If yes, specify the total amount (in Kilograms)

Item 9.5 Maximum possession limit for each radioisotope requested.

Item 9.6 Proposed use for each radioisotope requested.

PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

Item 10 Distribution And Redistribution Of Licensed Materials

Item 10.1 Radiopharmaceuticals (Check both boxes)

☐ We will confirm that radiopharmaceuticals will be prepared under the supervision of an ANP or will be obtained from a supplier authorized pursuant to **12VAC5-481-480 I**, or under equivalent NRC or other Agreement State requirements;

AND

☐ We will describe all licensed material to be distributed or redistributed.

Item 10.2 Generators (**Check all boxes if using generators)**

☐ Confirm that the generators will be obtained from a manufacturer licensed pursuant to **12VAC5-481-480 I**, or under equivalent NRC or other Agreement State requirements.

AND

☐ Confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging.

Item 10.3 Redistribution Of Generators (Check all boxes if redistributing generators)

☐ We will submit a description of the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of migration of radioactive fluids out of the generator during transport.

AND

☐ Confirm that the manufacturer's packaging and labeling will not be altered.

AND

☐ Confirm that the generator will not be distributed beyond the expiration date shown on the generator label.

AND

☐ Confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator.

AND

☐ Confirm that only generators used in accordance with the manufacturer's instructions will be redistributed.

Note: Although redistribution of used generators may be authorized by VDH, VDH approval does not relieve the licensee from complying with applicable FDA or other Federal or state requirements.

Item 10.4 Redistribution Of Sealed Sources – For Brachytherapy Or Diagnosis (Check all boxes if redistributing sealed sources, for brachytherapy or diagnosis)

☐ Confirm that the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued in pursuant to **12VAC5-481-480 J**, or under equivalent NRC or other Agreement State requirements.

AND

☐ Confirm that the manufacturer's packaging, labeling and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

Item 10.5 Redistribution Of Calibration And Reference Sealed Sources (Check all boxes if redistributing calibration and reference sealed sources)

☐ Confirm that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a person licensed pursuant to **12VAC5-481-480 J**, or under equivalent NRC or other Agreement State requirements, to initially distribute such sources.

AND

☐ Confirm that the manufacturer's labeling and packaging will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

Item 10.6 Redistribution Of Prepackaged Units For In-Vitro Tests (Check box if redistributing prepackaged units for In-vitro tests)

☐ Confirm that the prepackaged units for in-vitro tests to be redistributed will have been obtained from a manufacturer licensed to distribute the prepackaged units for in-vitro tests pursuant to **12VAC5-481-480 G**, or under equivalent NRC or other Agreement State requirements.

Item 10.7 Redistribution To General Licensee (Check all boxes if redistributing to a general licensee)

☐ Confirm that the manufacturer's packaging and labeling of the prepackaged units for in-vitro tests will not be altered in any way.

AND

☐ Confirm that each redistributed prepackaged unit for in-vitro tests will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees.

Item 10.8 Redistribution To Specific License (Check box)

☐ Confirm that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed prepackaged units for in-vitro test will NOT reference general licenses, exempt quantities, or VDH, NRC, or Agreement State regulations that authorize a general license.

PREPARATION OF RADIOPHARMACEUTICALS

Item 11 Preparation Of Radiopharmaceuticals (Check box)

☐ We will attach a document that indicates the types of radiopharmaceuticals preparation activities we intend to perform (e.g.; compounding of Iodine-131 capsules, radioiodination, and technetium-99m kit preparation). (Document is attached)

SERVICE ACTIVITIES

Item 12 Service Activities (Check box)

☐ We will submit specific procedures for all radiation protection services that we intend to provide to other licensees (e.g. customers). (Procedures are attached)

FACILITIES AND EQUIPMENT

Item 13 Facilities And Equipment (Check boxes and attach diagram.)

☐ We will provide copies of a license from the State Board of Pharmacy; or evidence that we are operating as a nuclear pharmacy within a state medical institution.

Note: There may be a jurisdiction that does not recognize the practice of commercial radiopharmacy. In these cases, the applicant must submit evidence that it is registered or licensed with the FDA as a drug manufacturer.

AND

☐ We will provide a description of the facilities and equipment to be made available where radioactive material will be used. A diagram should provide be submitted showing the entire facility and identify activities conducted in all contiguous areas surrounding the facility. Diagrams should be drawn to specified scale, or dimensions should be indicated. For additional information refer to VAREG 'Guidance for Commercial Radiopharmacy'. (Description is attached)

RADIATION SAFETY PROGRAM

Item 14 Radiation Safety Program

Item 14.1 Audit Program

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

Item 14.2 Radiation Monitoring Instruments (Check one box)

☐ We will use equipment that meets the radiation monitoring instrument specifications and implement the survey meter calibration program published in Appendix J of VAREG 'Guidance for Commercial Radiopharmacy'.

OR

☐ We will use equipment that meets the radiation monitoring instrument specifications published in Appendix J of VAREG 'Guidance for Commercial Radiopharmacy', and instruments will be calibrated by licensees authorized by VDH, the NRC or another Agreement State.

OR

☐ We will provide a description of alternative equipment to be used for radiation monitoring and alternative procedures for the calibration of radiation monitoring equipment. (Procedures are Attached)

Item 14.3 Material Receipt And Accountability (Check all boxes)

☐ We have developed, and will implement and maintain, written procedures for safely opening packages that meet the requirements in **12VAC5-481-900**.

AND

☐ We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed 6 months.

AND

☐ We have developed, and will implement and maintain written procedures for radioactive material accountability and control to ensure that:

1. License possession limits are not exceeded;
2. Radioactive material in storage is secured from unauthorized access or removal;
3. Radioactive material not in storage is maintained under constant surveillance and control; and
   Records of receipt, transfer, and disposal of licensed material are maintained.

(Procedures are attached)

Item 14.4 Occupational Dosimetry (Check all that apply)

☐ We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged at a frequency recommended by the processor.

AND / OR

☐ We will maintain for inspection by the agency, 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 **12VAC5-481-640**.

Item 14.5 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 14.6 Safe Use Of Radionuclidies And Emergency Procedures (Check box)

☐ We will develop, implement and maintain safe use of radionuclides and emergency procedures that meets the criteria in the section titled 'Safe Use of Radionuclides and Emergency Procedures' in VAREG 'Guidance for Commercial Radiopharmacy'. (Procedures are Attached)

Item 14.7 Surveys (Check one box)

☐ We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix R of VAREG 'Guidance for Commercial Radiopharmacy'.

OR

☐ We will develop, implement and maintain written procedures for a survey program that specifies the performance of radiation and contamination level surveys in restricted and unrestricted areas, personnel contamination monitoring, action levels, and the frequencies and records maintenance of those surveys and monitoring that meet the requirements in **12VAC5-481-100, 12VAC5-481-750 and 12VAC5-481-1000**. (Procedures attached)

Item 14.8 Dose Calibrator And Other Dosage Measuring Equipment (Check all that apply)

☐ We will describe the types of systems (measurement or combination of measurement and calculation) that we intend to use for the measurement of alpha-beta, and photon-emitting radioactive drugs.

AND

☐ We will develop, implement and maintain a written procedure for the performance of dose measurement system checks and tests that meet the requirements in **12VAC5-481-480 I**. (Procedures are attached)

AND EITHER

☐ We will provide, if applicable, a sample calculation for determining beta-correction factors for dose calibrators with ionization chambers.

OR

☐ We will include, if applicable, a means for ensuring the accuracy of beta-correction factors supplied by the instrument manufacturer, or other entity.

Item 14.9 Radioactive Drug Labeling For Distribution (Check both boxes)

☐ We will describe all labels, indicating the colors to be used, that will accompany the products and describe where each label is placed (e.g. on the "transport radiation shield" or the container used to hold the radioactive drug); (Description is attached)

AND

☐ Agree to affix the required labels to all "transport radiation shields" and each container used to hold the radioactive drugs.

Item 14.10 Radioactive Drug Shielding For Distribution (Check box)

☐ For each drug to be distributed, we will (except for products intended for redistribution without manipulation and in the manufacturer's original shipping package):

- Indicate the radionuclide and the maximum activity for each type of container (e.g. vial, syringe);
- Describe the type and thickness of the "transport radiation shield" provided for each type of container; and
- Indicate the maximum radiation level to be expected at the surface of each "transport radiation shield" when the radioactive drug container is filled with the maximum activity.

NOTE: It is not acceptable to State that the applicant will comply with DOT regulations. The dose rate limits that DOT imposes apply to the surface of the package, not the surface of the "Transport Radiation Shield."

Item 14.11 Leak Test (Check one box)

☐ 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 supplier's instructions.

License number of organization authorized to perform or analyze leak test (Specify whether VDH, NRC, or another Agreement State):

Organization Name: _____ License Number: _____
Issuing Agency: _____

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 another Agreement State.

OR

☐ We will perform our own leak testing and sample analysis. We will follow the procedures in Appendix L of VAREG 'Guidance for Commercial Radiopharmacy'.

OR

☐ We will submit alternative procedures. (Procedures are attached)

WASTE DISPOSAL AND TRANSFER

Item 15 Waste Disposal And Transfer

Item 15.1 Waste Management (Check box)

☐ We will develop, implement and maintain procedures for waste collection, storage and disposal by any of the authorized methods described in the section titled 'Waste Management' of VAREG 'Guidance for Commercial Radiopharmacy'. We will contact VDH for guidance to obtain approval of any method(s) of waste disposal other than those discussed in the section titled 'Waste Management' of VAREG 'Guidance for Commercial Radiopharmacy'. (Procedures are attached)

Item 15.2 Returned Waste From Customers (Check one box)

☐ We will follow the procedures for returned waste from customers in Appendix S of VAREG 'Guidance for Commercial Radiopharmacy'.

OR

☐ We will develop, implement and maintain procedures for returned waste from customers, that will meet the criteria in the section titled 'Returned Waste from Customers' in VAREG 'Guidance for Commercial Radiopharmacy'. (Procedures are attached)

SPECIFIC LICENSE FEE

Item 16 License Fees (12VAC5-490)

Category:	License fee enclosed ☐ Yes ☐ No Amount Enclosed

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

Item 17

I hereby certify that this application was prepared in conformance with 12VAC 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

Appendix B:

VDH Form,
'Certificate of Disposition of Materials'

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

CERTIFICATE OF DISPOSITION OF MATERIALS

Completion of this form is required to complete termination of a Radioactive Material License as outlined in **12VAC5-481-510**. Failure to provide information will result in this request for termination of a specific license not being processed.

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

CONTACT INFORMATION

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

TERMINATION AND DISPOSITION INFORMATION

The following information is provided in accordance with **12VAC 5-481-510.** (Check all that apply)

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

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

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

☐ Transferred to: Name Address

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

Issued by (Licensing Agency):

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

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

☐ Other (Attach additional pages)

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

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

Name:

Address:

Contact Person Telephone Number: ( ) - x

Additional remarks (Attach additional pages if necessary.)

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

Item 10.

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

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

Print Name and Title of above signatory

Appendix C:

Sample Delegation Letter

SAMPLE CORRESPONDENCE DELEGATION LETTER

[date]

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

To Director, Radioactive Materials Program:

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:

Reserved

Appendix E:

Reserved

Appendix F:

Information Needed for Transfer of Control Application

Information Needed for Transfer of Control Application

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

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

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

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

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

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

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

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

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

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

Appendix G:

Model Formats for Documenting Training and Experience for Individuals Responsible for Radiation Protection Program

Authorized User or Radiation Safety Officer Training In Basic Radioisotope Handling Techniques

Name (Last, First, Initial)								
Location of Training	**Dates**	**Title**	**Total Hours**	**Breakdown of Course in Clock Hours**				
				RPP	**BH**	**IR**	**INST**	**REG**
			Totals					

RPP **Radiation Protection Principles**

BH **Biological Hazards**

IR **Ionizing Radiation Units & Characteristics**

INST **Radiation Detection Instrumentation**

REG **VDH Rule**

Authorized User and Radiation Safety Officer Experience Handling Radioisotopes

(Actual use of radioisotopes under the supervision of an Authorized User or Radiation Safety Officer, respectively)

Name (Last, First, Initial)				
Isotope(s) Used	**Maximum amount Used at any one time**	**Location of Use**	**Purpose of Use***	**Total Hours of Experience**

*** Purpose of Use:**

- **Shipping, receiving, and performing related radiation surveys**
- **Using and performing checks for proper operation of dose calibrators, survey meters, and other instruments used to measure photon- and high energy beta-emitting radionuclides**
- **Using and performing checks for proper operation of instruments used to measure alpha- and low energy beta- emitting radionuclides**
- **Calculating, assaying, and safely preparing radioactive materials**
- **Use of procedures to prevent or minimize contamination and/or use of proper decontamination procedures**

Authorized Nuclear Pharmacist
Training in Basic Radioisotope Handling Techniques

Name (Last, First, Initial)

Location of Training	Dates	Title	Total Hours	Breakdown of Course in Clock Hours				
				RPP	BH	IR	INST	REG
			Totals					

Signature of Preceptor Authorized Nuclear Pharmacist: "I certify that the above described training/experience has been satisfactory completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy."	Signature:	Date:

RP **Radiation Protection Principles**
P

BH **Biological Hazards**

IR **Ionizing Radiation Units & Characteristics**

INST **Radiation Detection Instrumentation**

RE **VDH Rule**
G

Authorized Nuclear Pharmacist
Experience Handling Radioisotopes

(Actual use of radioisotopes under the supervision of an Authorized User or Radiation Safety Officer, respectively)

Name (Last, First, Initial)				
Isotope(s) Used	**Maximum amount Used at any one time**	**Location of Use**	**Purpose of Use***	**Total Hours of Experience**

Signature of Preceptor Authorized Nuclear Pharmacist: "I certify that the above training/experience has been satisfactory completed and that the individual has achieved a level of competency sufficient to independently operate a Nuclear Pharmacy."	**Signature:**	**Date:**

*** Purpose of Use**

- **Shipping, receiving, and performing related radiation surveys**
- **Using and performing checks for proper operation of dose calibrators, survey meters, and other instruments used to measure photon- and high energy beta-emitting radionuclides**
- **Using and performing checks for proper operation of instruments used to measure alpha- and low energy beta-emitting radionuclides**
- **Calculating, assaying, and safely preparing radioactive materials**
- **Use of procedures to prevent or minimize contamination and/or use of proper decontamination procedures**

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

TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION STATEMENT – G

(Authorized Nuclear Pharmacist)

The Virginia Department of Health is requesting disclosure of all information on this statement for the purpose of authorizing an individual to work with radioactive material. Failure to provide any information may result in denial or delay of authorizing an individual to work with radioactive material.

Instructions: Complete all applicable items. Refer to VAREG 'Guidance for Medical Use of Radioactive Material'. Use supplementary sheets where necessary. Retain one copy and submit original of the document to the Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219.

PART I TRAINING AND EXPERIENCE

Describe training and experience in sufficient detail to match the training and experience criteria in applicable regulations.

1. Name of Individual

2. State Licensure

☐ A copy of license to practice pharmacy in Virginia is attached.

3. Certification (attach copy of current certificate)

Specify Board	Category	Month and Year Certified

Note: Items 4-6 do not need to be completed when using Board Certification to meet **12VAC5-481 Part VII**, training and experience requirements.

4. Classroom and Laboratory Training

Description of Training	Training Location	*Clock Hours*	*Dates of Training*
Radiation Physics and Instrumentation			
Radiation Protection			
Mathematics Pertaining to Use and Measurement of Radioactivity			
Radiation Biology			

5. Supervised Work Experiences

Description of Experience	Dates of Experience
Shipping, receiving and performing radiation related surveys	
Using and performing checks for proper operation of survey meters and instruments used to determine the activity of dosages.	
Calculating, assaying and safely preparing dosages.	
Using administrative controls to avoid medical events in the administration of radioactive material.	
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures.	

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

6. Preceptor Approval and Attestation

☐ I am an authorized nuclear pharmacist.

I attest that the individual named in **Item 1**:

☐ Has satisfactorily completed the training requirements in **12VAC5-481-1770**;

AND

☐ Has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Name of License on which Preceptor is Authorized	Materials License Number –(Indicate which Agreement State or if NRC)
Print Name of Preceptor	
SIGNATURE - Preceptor	Date Signed

Appendix H:

Duties and Responsibilities of the Radiation Safety Officer

Duties and Responsibilities of the Radiation Safety Officer

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

- General surveillance is provided over all activities involving radioactive material; including routine monitoring, special surveys, and responding to events;
- Incidents are responded to, investigated and cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Proper authorities are notified of incidents such as damage, fire, or theft;
- Corrective actions are developed, implemented, and documented when violations of the rule or license conditions or program weaknesses are identified;
- Immediate termination of all activities following any unsafe condition or activity that is found to be a threat to public health and safety;
- Acts as the primary source of radiation protection information for personnel at all levels of responsibility;
- All radiation workers are properly trained;
- Procedures for the safe use of radioactive materials are developed and implemented;
- The licensee's procedures and controls, based upon sound radiation protection principles, are periodically reviewed to ensure that occupational doses and doses to members of the public are as low as is reasonably achievable (ALARA). Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit;
- Prospective evaluations are performed of occupational exposures and those individuals likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits are provided personnel monitoring devices;
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- The performance of fume hoods and gloveboxes used for volatile radioactive work are monitored for proper operation;
- The receipt, opening, and delivery of all packages of radioactive material arriving at the nuclear pharmacy are overseen and coordinated;
- An inventory of all radioactive materials is maintained and the types and quantities of radionuclides at the facility are limited to the forms and amounts authorized by the license;
- Sealed sources are leak-tested at required intervals;
- There is effective management of the radioactive waste program, including effluent monitoring;
- Packaging and transport of radioactive material is in accordance with all applicable VDH and DOT requirements;
- An up-to-date license is maintained and amendment and renewal requests and notifications of new ANP's are submitted in a timely manner;
- Radiation safety program audits are performed at least annually and documented;
- Acts as liaison to VDH; and
- All required records are properly maintained

Appendix I:

Suggested Commercial Radiopharmacy Audit Checklist

Suggested Commercial Radiopharmacy Audit Checklist

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 which do not apply to the licensee's activities and activities which have not occurred since the last audit need not be reviewed at the next audit.

Date of this Audit:_____ Date of last Audit:_____

Next Audit Date:_____

Auditor_____ Date_____
(Signature)

Management Review_____ Date_____
(Signature)

Audit History

A. Last audit of this location conducted on (date)_____

B. Were previous audits conducted at intervals not to exceed 12 months? (**12VAC5-481-630**)

C. Were records of previous audits maintained? (**12VAC5-481-990**)

D. Were any deficiencies identified during last two audits or two years, whichever is longer?

E. Were corrective actions taken? (Look for repeated deficiencies.)

Organization and Scope of Program

A. If the mailing address or places of use changed, was the license amended? (**12VAC5-481-500**)

B. If ownership changed or bankruptcy filed, was VDH's prior consent obtained or was VDH notified? (**12VAC5-481-500**)

C. Authorized Nuclear Pharmacists

1. New ANP since last audit? If so, does new ANP meet's VDH requirements? (**12VAC5-481-10; 12VAC5-481-480**)
2. If an individual began work as an ANP, was VDH notified within 30 days or was the license amended? (**12VAC5-481-480**)

D. Radiation Safety Officer

1. New RSO since last audit? If so, does new RSO meet VDH's training requirement?
2. If the RSO was changed, was license amended?
3. Is RSO fulfilling his/her duties?
4. To whom does RSO report to?

E. Authorized Users

1. New AU since last audit? If so, does new AU meet VDH's requirements?

2. If an AU was added, was the license amended?

F. If the designated contact person for VDH changed, was VDH notified?

G. Type and quantity of radioactive material

1. Does the license authorize all of the regulated radionuclides possessed?
2. Is actual possession of those radionuclides within the limits on the license?

Facilities

A. Are facilities as described in VDH's license application?

B. If facilities have changed, has the license been amended?

Equipment and Instrumentation

A. Sufficient numbers of portable and fixed radiation monitors (i.e., points of entry and exit into hotlab, package shipping area)?

B. Do survey meters meet VDH's criteria? (**12VAC5-481-750**)

C. Are calibration records maintained? (**12VAC5-481-1000**)

D. Are there sufficient lead shields (L-block, etc.) for work with radionuclides?

E. Are generators housed in separate room and/or properly shielded to keep doses ALARA?

F. Are procedures established for identifying, evaluating and reporting safety component defects?

G. Dose calibrators for Photon-emitters (**12VAC5-481-480**):

1. Constancy, at least once a day prior to assay of patient dosages (+/- 10%)?
2. Linearity, at installation and at required frequency (+/- 10%)?
3. Geometry dependence, at installation (+/- 10%)?
4. Accuracy, at installation and at required frequency (+/- 10%)?
5. After repair, adjustment, or relocation of the dose calibrator, were appropriate tests listed above repeated?

H. Dose Measurement Systems for Beta- and Alpha-emitters (**12VAC5-481-480**):

1. Calibrated for each isotope used, with that isotope?
2. Constancy, at least once each day, prior to assay of patient dosages (+/- 10%)?
3. Geometry dependence, at installation (+/- 10%)?
4. Accuracy, at installation and annually (+/- 10%)?
5. Linearity, at installation and quarterly (+/- 10%)?
6. After repair, adjustment, or relocation of the dose calibrator, were appropriate test above repeated?

Area Surveys and Contamination Control

A. Are area surveys being performed at applicable locations (i.e., hotlab and radioactive material storage locations) and required frequencies? Records maintained? (**12VAC5-481-1000**)

B. Are removable contamination surveys being performed at applicable locations and required frequencies? Records maintained? (**12VAC5-481-1000**)

C. Are appropriate corrective actions taken and documented when excess radiation or contamination levels are detected?

Leak Tests

A. Was each sealed source leak tested every six months or at other prescribed intervals?

B. Was the leak test performed according to the license?

C. Are records of results retained with the appropriate information included?

D. Were any sources found leaking if yes, was VDH notified?

Sealed Source Inventory

A. Is a record kept showing the receipt of each sealed source? (**12VAC5-481-100; 12VAC5-481-571**)

B. Are all sealed sources physically inventoried every six months?

C. Are records of inventory results with appropriate information maintained?

Training and Instructions to Workers

A. Were all workers who are likely to exceed 1mSv (100 mrem) in a year instructed annually per **12VAC5-481-2270**? Records maintained?

B. Were other workers trained as needed (e.g., radiopharmacy technicians, authorized users, couriers/drivers, ancillary personnel)? (**12VAC5-481-450**) Records maintained?

C. Are workers knowledgeable of applicable **12VAC5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation',** radiation protection procedures, emergency response procedures and license conditions?

D. HAZMAT training provided, if required? (**49 CFR 172.700-704**)

Material Use Control and Transfer

A. Are restricted and unrestricted areas delineated?

B. Are radioactive materials that are stored in a controlled or unrestricted area secured from unauthorized access or removal? (**12VAC5-481-840**)

C. Are radioactive materials that are in a controlled or unrestricted area and not in storage controlled and maintained under constant surveillance? (**12VAC5-481-840**)

D. Procedures for receiving and opening packages? (**12VAC5-481-900**)

E. Transfer of radioactive material only to authorized recipients? (**12VAC5-481-570**) Records of receipt and transfer? (**12VAC5-481-100**; **12VAC5-481-571**)

Personnel Radiation Protection

A. Are ALARA considerations incorporated into the radiation protection program? (**12VAC5-481-630**)

B. Were prospective evaluations performed showing that unmonitored individuals receive less than 10% of the limit? (**12VAC5-481-750**; **12VAC5-481-760**)

C. Did unmonitored individuals' activities change during the year which could put them over 10% of the limit?

D. If yes to C. above, was a new evaluation performed?

E. Is external dosimetry required (individuals likely to receive >10% of the limit)? And is dosimetry provided to these individuals?

1. Is the dosimetry supplier NVLAP approved? (**12VAC5-481-750**)
2. Are the dosimeters exchanged at appropriate frequency?
3. Are dosimetry reports reviewed by the RSO when they are received?
4. Are the records on VDH forms or equivalent? (**12VAC5-481-1020; 12VAC5-481-1040**) VDH form, 'Occupational Exposure Record for a Monitoring Period' completed?
5. Declared pregnant worker/embryo/fetus
   a. If a worker declared her pregnancy, did the licensee ensure that the dose to the embryo or fetus during the entire pregnancy was less than 5 mSv (500 mR)? (**12VAC5-481-710**) Were records kept of embryo/fetus dose per **12VAC5-481-1040**?

F. Monitoring for internal dose if individuals likely to receive >10% of ALI?

G. Are workers notified anually of their exposures?

H. Are records of exposures, surveys, monitoring, and evaluations maintained per **12VAC5-481-1000** and **12VAC5-481-1040***?*

Waste Management

A. Waste storage areas

1. Is storage area properly posted? (**12VAC5-481-860**)
2. Are containers properly labeled? (**12VAC5-481-880**)

B. Decay-in-Storage

1. Do radionuclides being stored all have half-lives less then 120 days (or 300 days if permitted by license condition)?
2. Are radionuclides being segregated for storage according to half-life?

3. Each radionuclide in radioactive waste stored for a minimum of 10 half-lives?

4. Before waste is disposed of:
   a. Survey performed at the container surface with an appropriate survey instrument set on its most sensitive scale with no interposed shielding to determine that its radioactivity cannot be distinguished from background?
   b. All radiation labels removed or obliterated, as appropriate?
5. Record Keeping?

C. Disposal by release into sanitary sewerage.

1. Is radioactive material readily soluble (or readily dispersible biologically material) in water? (**12VAC5-481-910; 12VAC5-481-930**)
2. Quantity of radioactive 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 **12VAC5-481-3690**?
3. If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit in **12VAC5-481-3690** does not exceed unity?
4. Total quantity of radioactive material released into the sanitary sewerage system in a year does not exceed the limits specified in **12VAC5-481-930**?

D. Transfer to Authorized Recipient

1. Is waste transferred to a person specifically authorized to receive it? (**12VAC5-481-570; 12VAC5-481-910)** Is waste properly manifested? (**12VAC5-481-1060)**

Receipt of Radioactive Waste from Customers

A. Waste returned consists only of items that contained radioactive materials that the radiopharmacy supplied (e.g., pharmacy supplied syringes, vials)?

B. Waste package checked for removable contamination upon receipt?

Effluents

A. Effluents from materials being maintained as low as reasonably achievable (ALARA)?

B. Fume hoods checked to confirm an adequate airflow?

C. Effluent monitored to determine activity being released?

D. Filters being maintained according to the manufacturer's instructions and pharmacy procedures?

Public Dose

A. Public access to radioactive materials and exposure to effluents controlled in a manner to keep doses below 1 mSv (100 mrem) in a year? (**12VAC5-481-720**)

B. Air emissions maintained below constraint limit of 0.1 mSv (10 mrem) in a year? (**12VAC5-481-630**)

C. Survey or prospective evaluation performed per **12VAC5-481-730**? 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. Unrestricted area radiation levels exceed 0.02 mSv (2mrem) in any one hour? (**12VAC5-481-720**)

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

Use and Emergency Procedures

A. Procedures for safe use of radioactive materials and emergency procedures developed and implemented?

B. Do the procedures contain the required elements?

C. Radioactive materials being handled safely?

D. Staff wearing protective clothing and personnel monitors as appropriate?

E. Assistance coordinated with outside agencies for emergency response (e.g., fire department, VDH)?

F. Did any emergencies occur?

1. If so, were they handled properly?
2. Were appropriate corrective actions taken?
3. Was VDH notification or reporting required? (**12VAC5-481-1090; 12VAC5-481-1100; 12VAC5-481-1110**)

Transportation

A. DOT-7A or other authorized packages used? (**49 CFR 173.415** and **49 CFR 173.416(b)**)

B. Package performance test records on file?

C. Package has two labels (ex. Yellow-II) with TI, Nuclide, Activity, and Hazard Class? (**49 CFR 172.403; 49 CFR 173.441**)

D. Package properly marked? (**49 CFR 172.301; 49 CFR 172.304; 49 CFR 172.310; 49 CFR 172.324**)

E. Package closed and sealed during transport? (**49 CFR 173.475(f)**)

F. Shipping papers prepared and used? (**49 CFR 172.200(a)**)

G. Shipping papers contain proper entries? (Shipping name, Hazard Class, Identification Number {UN Number}, Total Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity {SI units required}, category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, Emergency Response Information, and Cargo Aircraft Only {If applicable}) **(49 CFR 172.204; 49 CFR 172.604)**

H. Shipping papers within drivers reach and readily accessible during transport? **(49 CFR 177.817(e))**

I. Package secured against movement? **(49 CFR 177.834)**

J. Any incidents reported to DOT? **(49 CFR 171.15; 49 CFR 171.16)**

Auditor's Independent Survey Measurements (if made)

A. Describe the type, location, and results of measurements. Does any radiation level exceed regulatory limits? **(12VAC5-481-630; 12VAC5-481-720)**

Notification and Reports

A. Was any radioactive material lost or stolen? Were reports made? **(12VAC5-481-1090)**

B. Did any reportable incidents occur? Were reports made? **(12VAC5-481-1100; 12VAC5-481-1110)**

C. Did any overexposures and high radiation levels occur? Reported? **(12VAC5-481-1100; 12VAC5-481-1110)**

D. Were any contaminated packages or packages with surface radiation levels exceeding 200 mrem received? Reported to VDH?

E. If any events (as described in items A. through D. above) did occur, what was the root cause? Were appropriate notifications made and corrective actions taken?

F. Is the management/RSO aware of the emergency phone number for VDH (804-864-8150 during business hours, (800) 468-8892 after hours)?

Posting and Labeling

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

B. **12VAC5-481 'Virginia Radiation Protection Regulations', Part IV and X,** license documents and operating procedures posted or a summary of where to find the documents is posted? **(12VAC5-481-2260)**

C. Emergency procedures are posted in a conspicuous location?

D. Other postings and labeling? **(12VAC5-481-850; 12VAC5-481-860; 12VAC5-481-880)**

Record Keeping for Decommissioning

A. Records kept of information important to decommissioning? (**12VAC5-481-450 C**)

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

Information Notices

A. Are VDH Information Notices received?

B. Appropriate training and action taken in response?

Special License Conditions or Issues

A. Did auditor review special license conditions or other issues?

Deficiencies Identified in Audit; Corrective Actions

A. Summarize problems/deficiencies identified during audit.

B. If problems/deficiencies identified in this audit, describe corrective actions planned or taken by the facility. Include date(s) when corrective actions are implemented.

C. Provide any other recommendations for improvement.

Evaluation of Other Factors

A. Senior licensee management is appropriately involved with the radiation protection program and/or RSO oversight?

B. RSO has sufficient time to perform his/her radiation safety duties?

C. Licensee has sufficient staff to support the radiation protection program?

Appendix J:

Radiation Monitoring Instrument Specifications and Survey Instrument Calibration Program

The specifications in **Table 5** will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facility.

Table 5. Typical Survey Instruments (Instruments used to measure radiological conditions at licensed facility.)

Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	**Radiation**	**Energy Range**	**Efficiency**
Exposure Rate Meters	Gamma, X-Ray	millirem through Rem	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, 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 Flow Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	<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; and
- 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 to be within ± 5% accuracy 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 cesium-137 or 7.8×10^{2} megabecquerels (21 mCi) of cobalt-60].

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

- Linear readout instruments with a single calibration control for all scales shall be adjusted at the point recommended by the manufacturer or at a point within the normal range of use.

Instruments with calibration controls for each scale shall be adjusted on each scale. After adjustment, the response of the instrument shall be checked at approximately 20% and 80% of full scale. The instrument's readings shall be within ± 15% of the conventionally true values for the lower point and ± 10% for the upper point;

- Logarithmic readout instruments, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. The instrument shall be adjusted for each scale according to site specifications or the manufacturer's specifications. After adjustment, calibration shall be checked at a minimum of one point on each decade. Instrument readings shall have a maximum deviation from the conventionally true value of no more than
  10% of the full decade value;
- Meters with a digital display device shall be calibrated the same as meters with a linear scale;
- Readings above 2.58 X 10^{-4} coulomb/kilogram/hour (1 R/hr) need not be calibrated, but such scales should be checked for operation and response to radiation; 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 to be within ± 5% accuracy by National Institutes of Standards and Technology
  (NIST); and
- Approximate the same energy and type of radiation as the samples that the calibrated device will be used to measure.

Calibration

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

Calibration Records

Calibration reports, for all survey instruments, will indicate the procedure used and the data obtained. The description of the calibration will 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 will be attached to the instrument as a calibration sticker or tag:

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

Frequency of Calibration

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

Error Limit for Measurement of Air Sample Volume

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

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

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

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 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 accuracy's 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:

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

Note: The calibration factor should be based on two kinds of determinations. First, correction factors should be determined at several flow rates distributed over the full-scale range. Each flow rate correction factor should be determined while adjusting flow rates upscale and again while adjusting flow rates downscale, and the two sets of data should be compared. Second, subsequent calibrations should compare the new correction factor to those determined during the previous calibration. If observed differences are significant compared to the overall volume error limit of 20%, an additional error term should be included in the calculation above.

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

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

Where: Vs = volume at standard conditions (760 mm & 0 degree C)
V1 = volume measured at conditions P1 and T1
T1 = temperature of V1 in K
P1 = pressure of V1 in mm Hg

Documentation of Calibration of Air Metering Devices

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

References: NRC Regulatory Guide 8.25, Revision 1, 'Air Sampling in the Workplace', dated June 1992; and NUREG – 1400, 'Air Sampling in the Workplace', dated September 1993.can be accessed at the NRC website www.nrc.gov.

Additional References:

1. The Health Physics & Radiological Health Handbook, Revised Edition, Edited by Bernard Shleien, dated 1992.
2. 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: www.ansi.org;
3. 'Air Sampling Instruments', American Conference of Governmental Industrial Hygienists, 7th Edition, dated 1989.

Appendix K:

Public Dose

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

Licensees must ensure that:

- The radiation doses received by individual members of the public do not exceed 1 millisievert (mSv) [100 millirem (mrem)] in one calendar year resulting from the licensee's possession and/or use of licensed materials. (**12VAC5-481-720**);
- Air emissions of radioactive material to the environment will not result in exposures to individual members of the public in excess of 0.1 mSv (10 mrem) (TEDE) in one year from those emissions. (**12VAC5-481-630**); and
- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour. (**12VAC5-481-720**)

Note: Members of the public include persons who live, work, 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 who work in the vicinity where such materials are used or stored.

Doses to Members of the Public INCLUDES doses from:

- Radiation and/or radioactive material released by a licensee
- Sources of radiation under the control of a licensee
- Air effluents from sources of licensed radioactive materials
- Licensed material in transportation or storage at the licensee's facility

BUT, DOES NOT INCLUDE doses from:

- Sanitary sewerage discharges from licensees
- Natural background radiation
- Medical administration of radioactive material
- Voluntary participation in medical research

Note: Typical unrestricted areas may include offices, shops, 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. However, the licensee may control access to these areas for other reasons such as security.

The licensee may show compliance with the annual dose and constraint limits 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) from all exposure pathways, and does not exceed 0.1 mSv (10 mrem) from air emissions.;
- Demonstrating that the annual average concentration of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area does not exceed the values specified in **12VAC5-481-3690, Table 2** (20% of the values for gaseous effluents); and
- If an individual were continuously present in an unrestricted area the dose from external sources would not exceed 0.02 mSv (2 mrem) in an hour and 0.5 mSv (0.05 rem) in a year.

In order to perform a dose assessment, the licensee should identify all potential sources of external and internal radiation exposure to members of the public and all locations of use,

transport, and storage of radioactive material at their facility. The licensee must then take radiation measurements or perform calculations to demonstrate compliance.

Measurements

The licensee may use measurements 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) and does not exceed 0.1 mSv (10 mrem) from air emissions. 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. At radiopharmacies, airborne effluents are discharged when potentially volatile materials are used, such as during iodine capsule preparation, but the discharge itself is usually not continuous since volatile materials are 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, 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. This 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 6**). If the result of the calculation using an occupancy factor of 1 demonstrates that the public dose and constraint limits are not exceeded, then there is no need for further evaluation.

If the calculation demonstrates that either the public dose or constraint 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 must be made. The licensee may use the occupancy factors in **Table 6** or may calculate a specific occupancy factor by determining the likely fraction of time that the individual is present.

Table 6: 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

Calculating the Annual Dose to an Individual Member of the Public:

- Identify all potential sources of external and internal exposure to the member of the public.
- Identify all locations of use, transport, or storage of radioactive material.
- Perform surveys of all locations of use, transport, or storage of radioactive material.
- Identify from survey data, at each location, maximum levels of dose rates.
- Calculate predicted occupancy factors at points of maximum dose rates.
- Multiply dose rates by number of hours in a year to produce the maximum annual dose.
- Multiply the maximum annual dose by the occupancy factors to get the annual dose.

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 L:

Leak Test Program

Training

Before allowing an individual to perform leak testing, the licensee must ensure that he or she has sufficient classroom and on-the-job training to show competency in performing leak tests independently.

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:

- Observing authorized personnel collecting and analyzing leak test samples; and
- Collecting and analyzing leak test samples under the supervision and in the physical presence of an individual authorized to perform leak tests

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests will be analyzed in a low-background area.
- Use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed.
- Analyze the leak test sample using an instrument that is appropriate for the type of radiation to be measured (NaI(Tl) well counter system, liquid scintillation, gas flow proportional counter).
- If the sensitivity of the counting system is unknown, the minimum detectable activity (MDA) needs to be determined. The MDA may be determined using the following formula:

$$MDA = \frac{3 + 4.65(bkg/t)^{1/2}}{E}$$

Where: MDA = minimum detectable activity in disintegration's per minute (dpm)
bkg = background count rate in counts per minute (cpm)
t = background counting time in minutes
E = detector efficiency in counts per disintegration

For example:

Where: bkg = 200 cpm
E = 10%, or 0.1
t = 2 minutes

$$MDA = \frac{3 + 4.65(200 \text{ cpm}/2 \text{ minutes})^{1/2}}{(0.1)}$$

$$= 495 \text{ dpm}$$

Frequency for Conducting Leak Tests of Sealed Sources

Leak tests will be conducted at the frequency 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 sealed source serial number, radionuclide, 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 where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 185 Bq (0.005 microcuries) of the radionuclide.
- Using the selected instrument, count and record background count rate.
- Check the instrument's counting efficiency using a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within ± 5% of the stated value and traceable to primary radiation standard such as those maintained by the National Institutes of Standards and Technology (NIST).
- Calculate efficiency.

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

  For example: $\frac{\text{[(cpm from wipe sample) - (cpm from bkg)]}}{\text{efficiency in cpm/Bq}}$ = Bq on wipe sample
- Sign and date the list of sources, data, and calculations. Retain records for 5 years (**12VAC5-481-1010**). If the wipe test activity is 185 Bq (0.005 microcurie) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly. Also notify VDH.

Appendix M:

Transportation: DOT Regulations Applicable to Radiopharmacy Shipments

The major areas in the DOT regulations most relevant to commercial radiopharmacies for the transportation of radioactive material are:

- Hazardous Materials Table, **49 CFR 172.101, App. A**, list of hazardous substances and reportable quantities (RQ), Table 2: Radionuclides.

  For the majority of packages shipped by radiopharmacies to their customers, the proper shipping name to use will be "*Radioactive Material, N.O.S.*" Other shipments, involving primarily small quantities of radioactive material, and especially return shipments by customers, will likely be excepted packages of limited quantity. The DOT requirements for those shipments can be found in **49 CFR 173.421** and **173.422**.

  Likewise, for the majority of packages shipped by radiopharmacies, it will not be necessary to identify the radioactive material as a Hazardous Substance in accordance with **Table 2 of 49 CFR 172.101**. For the majority of radionuclides contained in packages from radiopharmacies (i.e., Technetium-99m and Thallium-201) the threshold for identification as a Hazardous Substance is on the order of 100 to 1000 curies, which is significantly more than is contained in the typical shipment. However, for shipments containing more than 10 millicuries of Iodine-131, the packages and shipping papers must include the "*RQ*" designation of the shipment as containing a reportable quantity. The "*RQ*" must appear either before or after the basic description of the shipment on the shipping papers (i.e., "*RQ Radioactive Material, N.O.S., UN 2982*") and must be included in the package markings (Ref. **49 CFR 172.203(c)** and **49 CFR 172.324**).

- Shipping Papers **49 CFR 172.200-204**: General entries, description, additional description requirements, and shipper's certification.

  For most packages likely to be shipped by commercial radiopharmacies shipping papers are required. These must include:
  - proper shipping name (as described above);
  - hazard class of the material; for radioactive materials, the hazard class is 7;
  - identification number; for the proper shipping name, "*Radioactive Material, N.O.S.*", the identification number is UN 2982;
  - package type, which will usually be Type A;
  - name and quantity of each radionuclide in the shipment; the radionuclide may be abbreviated (i.e., Tc-99m);
  - physical and chemical form of the radioactive material;
  - category of label applied to each package in the shipment (i.e., "*Radioactive White-I*");
  - transport index (TI) of each package bearing Radioactive Yellow-II or Radioactive Yellow-III labels;
  - emergency response telephone number; and
  - shipper's certification and signature.

  Shipping papers may include additional information; however, the additional information must not detract from the required entries.

  For most, if not all, return shipments of wastes from radiopharmacy customers, the packages can be shipped as excepted packages (limited quantity of radioactive material) and will not require shipping papers; however, such shipments must include a statement on, in, or transported with, the package. The statement is contained in **49 CFR**

173.422(a)(1), and must be verbatim. Although the proper preparation of the package of returned waste is the responsibility of the shipper (i.e., the customer), radiopharmacies should be aware of the specific requirements if they intend to provide guidance to their customers regarding these types of shipments.

- Package Markings **49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324**: General marking requirements for non-bulk packaging, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging

  All certification packages shipped by commercial radiopharmacies (i.e., Type A packages) must be properly marked, as follows:
  - proper shipping name and identification number (i.e., "*Radioactive Material, N.O.S., UN 2982*");
  - the letters RQ if the packages contain a hazardous substance, which will only likely occur when the packages contain more than 10 millicuries of Iodine-131; and
  - the designation Type A, if the package conforms to the Type A requirements.

  DOT also specifies the size and appearance of the markings and markings that are prohibited.

- 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.

  All packages routinely prepared and shipped by commercial radiopharmacies are required to be labeled in accordance with DOT regulations. The labels will usually be either "*Radioactive White-I*" or "*Radioactive Yellow-II*". Radiopharmacies have rarely offered a package labeled as "*Radioactive Yellow-III*" for shipment. Packages exhibiting surface radiation levels equal to or less than 0.5 millirem per hour will be labeled as "*Radioactive White-I*". There is no TI, defined as a unitless number equivalent to the radiation level, in millirems per hour, at one meter from the surface of the package, for a White-I label. Packages with surface radiation levels greater than 0.5 millirem per hour, but less than or equal to 50 millirems per hour, will be labeled with a Yellow-II label. The TI for a Yellow-II label must be less than or equal to 1. The lowest TI is 0.1, and all TIs are rounded to the nearest tenth.

  Packages required to be labeled must have two labels affixed, on opposite sides, but not on the top or bottom. The labels must include the identity and quantity of the radionuclides in the package. Yellow-II and Yellow-III labels must also include the TI. A label may not be affixed to a package that does not meet the applicable labeling requirements.

- Placarding of Vehicles **49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506,49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556**: Applicability, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, specifications for RADIOACTIVE placards.

DOT regulations specify when vehicles carrying hazardous materials must be placarded. For radiopharmacy shipments, this is usually applicable only when packages with Yellow-III labels affixed are offered or transported. Since commercial radiopharmacies rarely, if ever, offer Yellow-III packages for transport, placarding of the vehicles is not of concern and will not be discussed in detail.

- 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.

  Persons, who offer hazardous materials for transport including radioactive materials, must provide or make available emergency response information, including:
  - An emergency response telephone number must be included on the shipping papers and the number must be monitored at all times that the material is being transported. The person monitoring the telephone number must be either knowledgeable of the hazardous material being shipped, or have comprehensive emergency response and incident mitigation information for that material, or have immediate access to a person who has such knowledge and information; and
  - Emergency response information for the shipment that will aid emergency responders in mitigating the consequences of an accident, including the health hazards of the material, handling fires and spills involving the material, and first aid measures must be included on, or with, the shipping papers.

  Applicants and licensees should review the specific DOT requirements applicable to emergency response information in the development of their programs and procedures.

- Training, **Subpart H, 49 CFR 172.700, 49 CFR 172.702; and 49 CFR 172.704**; Purpose and Scope, applicability and responsibility for training and testing, training requirements.

  Licensees who prepare packages of radioactive materials and who transport their own packages must provide training to their employees who perform those functions. The training must include:
  - General awareness and familiarization training designed to provide familiarity with DOT requirements, and enable the employee to recognize and identify hazardous materials;
  - Function-specific training concerning the DOT requirements which are specifically applicable to the functions the employee performs (i.e., if the employee's duties require him/her to affix DOT Radioactive labels to packages, he or she must receive training in DOT's regulations governing package labeling); and
  - Safety training concerning emergency response information, discussed above; measures to protect the employee and other employees from the hazards associated with the hazardous materials to which they may be exposed in the workplace; and methods of avoiding accidents, such as the proper procedures for handling packages containing hazardous materials.

  The training must be provided initially and then every three years. Records of training must be maintained.

- 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**: Definitions, general design requirements, additional design requirements for Type A packages, authorized Type A packages, activity limits for Type A packages, requirements for determining A_1 and A_2, table of A_1 and A_2 values for radionuclides, radiation level limitations, contamination control, general transportation requirements, quality control requirements prior to each shipment.

- Carriage by Public Highway - General Information and Regulations, **Subpart A, 49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834, 49 CFR 177.842**: Driver training, shipping paper, general requirements (secured against movement), Class 7 (radioactive) material.

  Licensees who intend to transport their own packages must ensure that their drivers receive training in the safe operation of the vehicle transporting the hazardous material packages. The training requirements include, but are not limited to:
  - Pre-trip safety inspection of the vehicle;
  - Requirements pertaining to vehicle attendance and incident reporting; and
  - Loading and unloading of the materials, including blocking and bracing the packages and separation from occupied compartments.

  The specific training requirements are located in **49 CFR 177.816**.

  The licensee must also ensure that its drivers maintain the shipping papers accessible during transport and when the driver is not at the vehicle controls. During transport, the shipping papers must be located within the driver's reach while restrained by the lap belt -- either in a pocket in the driver's door of the vehicle or readily visible to someone entering the driver's compartment. In an accident, emergency responders are instructed to look in those locations for the shipping papers to aid in handling the hazardous material aspects, if any. Failure to properly locate shipping papers could adversely impact the response to an accident, result in actions that spread radioactive contamination, and result in unnecessary radiation exposures to the responders. When the driver is not at the vehicle controls, such as during deliveries to customers, the shipping papers for the packages remaining in the vehicle must be either in the pocket in the driver's side door or on the driver's seat in the vehicle.

  49 CFR 177.834(a) and 177.842 require that packages of radioactive materials be blocked and braced so that they cannot change position during conditions normally incident to transportation. The method used must prevent lateral movement of the packages during normal transport conditions (turns, curves, potholes, dips, stopping and acceleration, etc.). This does not include accident situations. The key test for evaluating the effectiveness of blocking and bracing is to attempt to move the package by hand after it is loaded. If the package can be moved through normal (non-Herculean) effort, then it is not properly blocked and braced. The use of a non-skid material on the vehicle surface where the package is loaded is not sufficient by itself. Additional means are necessary to block the package within the vehicle.

Package Activity Limits

Before offering a radioactive materials package for transport, the shipper must determine the category of the shipment. Licensees will likely prepare or transport two categories of packages

containing radioactive material. The categories are based, in part, on the activity of the radioactive material contained in the package. The categories, activity ranges, packaging requirements, and examples are provided in **Table 7**. All quantities referenced here are multiples of the A_2 (normal form) values specified for radionuclides in **49 CFR 173.435** and the physical form is assumed to always be liquid.

Table 7: Package Activity Limits

Category	Activity Range	Packaging Requirements	Example
Excepted packages, limited quantity of radioactive material	Less than 10^{-4} A_2	**49 CFR 173.421 and 173.422**	Less than 21.6 millicuries of technetium-99m (usually for returned waste shipments)
Radioactive Material, N.O.S.	Greater than 10^{-4} A_2 but less than A_2	**Type A packaging (49 CFR 173.410; 49 CFR 173.412; 49 CFR 173.415; 49 CFR 173.431; 49 CFR 173.433)**	More than 21.6 millicuries, but less than 216 curies of technetium-99m

Once the quantity of material in the package has been determined, the appropriate packaging must be selected.

Packaging Design

Packages of radioactive material offered as excepted packages, limited quantity of radioactive material, in accordance with **49 CFR 173.421**, are required to meet the minimum packaging requirements of **49 CFR 173.410**. Those requirements primarily address, but are not limited to, maintaining package integrity and contents during conditions normally expected to occur during transport. This does not include survival during accidents. Packaging normally used by commercial radiopharmacies (i.e., military ammunition boxes, 'briefcases', and cardboard/fiberboard boxes, typically meet and exceed those minimal requirements).

Packages containing "*Type A*" quantities must meet more stringent criteria, including testing to demonstrate that the packages will maintain their integrity of containment and shielding during normal conditions of transport. The testing criteria for Type A packages are listed in **49 CFR 173.465**. Before offering a Type A package for shipment, the shipper is responsible for ensuring that the package has been tested to meet the criteria for the contents and the configuration to be shipped and maintaining a certificate of testing. Shippers are not required to personally test the packages, only to ensure that the testing was performed before use.

Quality Control

Prior to each shipment, the shipper is required to determine that the package is in condition for shipment. The determinations must include, but are not limited to verification of the following:

- Package is proper for the contents to be shipped;
- Packaging is in unimpaired physical condition; and
- External radiation and contamination levels are within the allowable limits.

The quality control requirements for radioactive material packages are located in **49 CFR 173.475**.

The external radiation and contamination level limits are located in **49 CFR 173.441** and **173.443**. The applicant should ensure that its procedures for preparing radioactive material packages include provisions to survey the handle on ammunition boxes and briefcases used as packaging, in addition to the closure clasp on ammunition boxes. Excessive contamination has been identified in those locations in several package contamination events reported in the past.

Hazard Communications for Class 7 (Radioactive) Materials

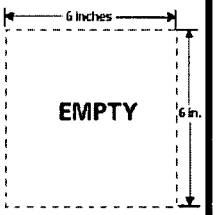
Labeling Packages (49 CFR 172.400-450)

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

Placement of Radioactive Labels

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

Determination of Required Label

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

Content on Radioactive Labels

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

Some Special Considerations/Exceptions for Labeling Requirements

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

Hazard Communications for Class 7 (Radioactive) Materials

Placarding Vehicles (49 CFR 172.500-560)

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

Visibility and Display of Radioactive Placard

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

Conditions Requiring Placarding

- Placards are required for any vehicle containing package with a RADIOACTIVE Yellow-III label
- Placards are required for shipment of LSA or SCO required by §173.427 to be consigned as exclusive use. Examples of this category are domestic, strong-tight containers with less than an A_2 quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52. Also, for bulk packages of these materials, the orange panel *marking* with the UN Identification number is not required.
- Placards are required any vehicle containing package with a Highway Route Controlled Quantity (**HRCQ**). In this case, the placard must be placed in a square background as shown below (see §173.507(a))

Radioactive Placard

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

Some Special Considerations/Exceptions for Placarding Requirements

- Domestically, substitution of the UN ID number for the word "RADIOACTIVE" on the placard is prohibited for Class 7 materials. However, some import shipments may have this substitution in accordance with international regulations.
- Bulk packages require the orange, rectangular panel marking containing the UN ID number, which must be placed adjacent to the placard (see §172.332) [NOTE: except for LSA/ SCO exclusive use under §173.427, as above]
- If placarding for more than one hazard class, subsidiary placards must not display the hazard class number. Uranium Hexaflouride (UF_6) shipments ≥ 454 kg (1001 lbs) require both RADIOACTIVE and CORROSIVE (Class 8) placarding
- For shipments of radiography cameras in convenience overpacks, if the overpack does not require a RADIOACTIVE - YELLOW III label, vehicle placarding is not required (regardless of the label which must be placed on the camera)

Appendix N

Model Personnel Training Program

Training Program

1. General Instructions

   1.1. Training will be provided:
   - Before an employee assumes duties with, or in the immediate vicinity of, radioactive materials;
   - At least annually, as refresher training for all employees; and
   - Whenever a significant change occurs in duties, regulations, or the terms of a VDH license.

   1.2 Subjects covered for individuals working with, or in the vicinity of, radioactive materials or radiation:
   - Safe radiation practices associated with the job (examples of topics that may be covered are found in Section 3 of this Appendix);
   - Site-specific radiation safety practices; and
   - Applicable VDH rule.

   1.3 Subjects covered for ancillary personnel:
   - Significance of the radiation symbol and its use on signs and labels;
   - Location of unrestricted areas; and
   - Whether the individual is authorized access to the restricted areas of the pharmacy.

   1.4. Type of instruction:
   - Instruction in the licensee's site-specific radiation safety program and VDH regulatory requirements may be in the form of lecture, demonstrations, videotape, or self study, and should emphasize practical subjects important to the safe use of radioactive material; and
   - Individuals receiving instructions should be provided an opportunity to ask questions.

2. Instruction for individuals likely to receive an occupational dose in excess of 100 mSv (100 mrem)

   2.1 Instruction will be provided:
   - Before an employee assumes duties with or in the immediate vicinity of radioactive materials;
   - At least annually, as refresher training; and
   - Whenever a significant change occurs in duties, rules, or terms of VDH license.

   2.2 Licensee must provide instruction in subjects covered in **12VAC5-481-2270**

   2.3 Records of initial and refresher training should be maintained and should include:
   - Name of the individual who provided the instruction;
   - Names of the individuals who received the instruction; and
   - Date of instruction and list of topics covered.

3. Suggested radiation safety training topics for individuals working with, or in the vicinity of, radioactive material (this section is intended as a guide to topics covered in a typical radiation safety training program; topics selected should be commensurate with the individuals' duties).

   3.1 Basic radiation safety information:
   - Basic radiation biology (e.g., interaction of ionizing radiation with cells and tissues);
   - Radiation safety
     - Radiation vs. contamination
     - Internal vs. external exposure;
     - Biological effects of radiation;

  - ALARA concept; and
  - Use of time, distance, and shielding to minimize exposure;
- Risk estimates, including comparison with other health risks (**12VAC5-481-2270**);
- Regulatory requirements;
  - RSO;
  - Material control and accountability;
  - Dose to individual members of the public;
  - Personnel dosimetry;
  - Occupational dose limits and their significance;
  - Dose limits to the embryo/fetus, including instruction on declaration of pregnancy;
  - Workers' right to be informed of occupational radiation exposure;
  - Radiation safety program audits;
  - Ordering and receipt of packages;
  - Transfer;
  - Waste disposal;
  - Recordkeeping;
  - Surveys;
  - Postings;
  - Labeling of containers;
  - Handling and reporting of incidents or events;
  - Licensing and inspection by VDH;
  - Need for complete and accurate information;
  - Employee protection; and
  - Deliberate misconduct

3.2. General topics for safe use of radioisotopes:

- Wear a laboratory coat or other protective clothing at all times when working with radioactive materials;
- Use syringe shields and vial shields when preparing and handling radioactive drugs;
- Measure all radiopharmaceuticals prior to transfer;
- Measure the molybedenum-99 content of each generator elution and do not transfer those radiopharmaceuticals for human medical use that will contain more then 0.15 microcuries of molybedenum-99 per mCi of technetium-99m at the time of administration;
- Wear disposable gloves at all times when handling radioactive materials and change gloves frequently to minimize the spread of contamination;
- Before leaving the hot lab, monitor hands, shoes, and clothing for contamination in a low-background area, allowing sufficient time for instrument response;
- Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used;
- Do not store food, drink, or personal effects in areas where radioactive material is stored or used. Personnel items brought into the restricted area (i.e., radios, compact discs, notepads, books, etc.) should be surveyed for contamination before removal from the area;
- Food and beverages used in the preparation of radiopharmaceuticals should be clearly labeled "*Not for personal consumption*" if stored with radioactive materials;
- Wear personnel monitoring devices, if required, at all times while in areas where radioactive material is 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 radioactive material when it is not under the constant surveillance and immediate control of the user(s).

3.3. Instruction on radiopharmacy-specific program elements:

- Applicable rules and license conditions;
- Areas where radioactive material is used or stored;
- Potential hazards associated with radioactive material in each area where the individuals will work;
- Special procedures for handling volatile materials;
- Proper use of radiation shielding;
- Proper use of survey and analytical instruments;
- Appropriate response to spills, emergencies, or other unsafe conditions;
- Emergency procedures;
- Previous incidents, events, and/or accidents;
- Survey program;
- Effluent monitoring and control;
- Customer-returned waste pickup, receipt, and handling;
- Waste management and minimization;
- Personnel monitoring;
- Procedures for receiving packages containing radioactive materials;
- Procedures for opening packages;
- Sealed sources and leak tests; and
- Other topics, as applicable.

Appendix O:

Model Dose Calibrator Testing Program

Model Procedures for Testing Dose Calibrators Used to Measure Photon-emitting Radionuclides

This model procedure can be used by applicants and licensees for checking and testing done calibrators.

1. Test for the following at the indicated frequency. Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances.
   1.1. Constancy, at least once each day prior to assay of patient dosages (a safe margin is considered to be below ±10%).
   1.2. Linearity at installation and at least quarterly thereafter (a safe margin is considered to be below ±10%).
   1.3. Geometry dependence at installation (a safe margin is considered to be below ±10%).
   1.4. Accuracy, at installation and at least annually thereafter (a safe margin is considered to be below ±10%).
2. After repair, adjustment, or relocation of the dose calibrator, such that proper function of the ionization chamber or electronics would likely be in doubt, repeat the above tests as appropriate.
3. Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cesium-137, Cobalt-60, Cobalt-57, or Radium-226 using a reproducible geometry each day before using the calibrator; consider using two or more sources with different photon energies and activities.
   Use the following procedure:
   3.1. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cesium 137 setting to assay Cesium-137).
   3.2. Measure background at the same setting and subtract or confirm the proper operation of the automatic background circuit if it is used.
   3.3. For each source used either plot or log (i.e., record in the dose calibrator log book) the background level for each setting checked and the net activity of each constancy source.
   3.4. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
   3.5. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the authorized nuclear pharmacist or the radiation safety officer of a suspected malfunction of the calibrator. These action levels should be written in the log book or posted on the calibrator. The dose calibrator should be repaired or replaced if the error exceeds 10%.
4. The linearity of a dose calibrator should be ascertained over the range of its use between the maximum activity in a vial and 30 microcuries. Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This example uses a vial of Technetium-99m that has the anticipated maximum activity to be assayed (e.g., the first elution from a new generator) and assumes your predetermined safety margin is ±5%.
   4.1. Time Decay Method
      4.1.1. Inspect the instrument to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).
      4.1.2. Assay the Technetium-99m vial in the dose calibrator and subtract background to obtain net activity in millicuries.
      4.1.3. Repeat step 4.1.2. at time intervals of 6, 24, 30, and 48 hours after the initial assay.

4.1.4. Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

Assay Time[4] (hours)	Correction Factor
0	31.6
6	15.8
24	2.00
30	1.00
48	0.126

[4] Assay times should be measured in whole hours and correction factors should be used to three significant figures as indicated. The half-life of $T_{1/2} = 6.02$ hours has been used in calculating these correction factors.

Example: If the net activity measured at 30 hours was 15.6 mCi, the calculated activities for 6 and 48 hours would be 15.6 X 15.9 = 248 mCi and 15.6 mCi X 0.126 = 1.97 mCi, respectively.

4.1.5. Plot both the measured net activity and the calculated activity versus time.

4.1.6. On the graph, the measured net activity plotted should be within ± 5% of the calculated activity if the instrument is linear and functioning properly. If variations greater than 5% are noted, adjust the instrument, have it repaired, or use arithmetic correction factors to correct the readings obtained in daily operations.

4.2 Shield Method: If a set of "sleeves" of various thicknesses are used to test for linearity, it will first be necessary to calibrate them.

4.1.1 Begin the linearity test by assaying the Technetium-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date and time to the nearest minute, and net activity. This first assay should be done in the morning at a regular time. After making the first assay, the sleeves can be calibrated as follows (steps 4.2.2. through 4.2.4 must be completed within 6 minutes).

4.1.2 Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

4.1.3 Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

4.1.4 Continue for all sleeves.

4.1.5 Complete the following decay method linearity test steps:

4.1.5.1 Repeat the assay at about noon, and again at about 4:00 p.m. Continue on subsequent days until the assayed activity is less than 30 millicuries. For dose calibrators on which the range is selected with a switch, select the range normally used for the measurement.

4.1.5.2 Convert the time and date information recorded to hours elapsed since the first assay.

4.1.5.3 On a sheet of semilog graph paper, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Plot the data.

4.1.5.4 Draw a 'best fit' straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.
(A-observed) – (A-line) / (A-line) = deviation.

4.1.5.5 If the worst deviation is more than ± 0.05 , the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph.

4.1.6 From the graph made in step 4.2.5.3, find the decay time associated with the activity indicated with sleeve 1 in place. This is the 'equivalent decay time' for sleeve 1. Record that time with the data received in step 4.2.2.

4.1.7 Find the decay time associated with the activity indicated with sleeve 2 in place. This is the 'equivalent decay time' for sleeve 2. Record that time with the data received in step 4.2.3.

4.1.8 Continue for all sleeves.

4.1.9 The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.
The sleeve set may now be used to test dose calibrators for linearity.

4.1.10 Assay the Technetium-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the net activity.

4.1.11 Steps 4.2.12 through 4.2.14 below must be completed within 6 minutes.

4.1.12 Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

4.1.13 Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

4.1.14 Continue for all sleeves.

4.1.15 On a sheet of semilog graph paper, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the model number and serial number of the dose calibrator.

4.1.16 Plot the data using the equivalent decay time associated with each sleeve.

4.1.17 Draw a 'best fit' straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.
(A-observed) – (A-line) / (A-line) = deviation.

4.1.18 If the worst deviation is more than ± 0.05 , the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow conversion from activity indicated by the dose calibrator to 'true activity'.

5. Geometry independence means that the indicated activity does not change with volume or configuration. The test for geometry independence should be conducted using syringes and vials that are representative of the entire range of size, shape, and constructions normally used for injections and a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following examples assumes that injections are done with 3-cc

plastic syringes, that radiopharmaceutical kits are made in 30-cc glass vials, and that the predetermined safety margin is ± 5% .

5.1 In a small beaker or vial, mix 2 cc of a solution of Technetium-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second beaker or vial with nonradioactive saline. Tap water may be used.

5.1 Draw 0.5 cc of the Technetium-99m solution into the syringe and assay it. Record the volume and millicuries.

5.2 Remove the syringe from the calibrator, draw an additional 0.5 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

5.3 Repeat the process until a volume of 2.0 cc has been assayed. The entire process must be completed within 10 minutes.

5.4 Select as a standard the volume closest to that normally used for injections. For all other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, graph the data and draw horizontal error lines above and below the chosen 'standard volume'.

5.5 If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the error lines, it will be necessary to make a correction table or graph that will allow a conversion from 'indicated activity' to 'true activity'. If this is necessary, be sure to label the table or graph 'syringe geometry dependence', and note the date of the test and model and serial number of the calibrator.

5.6 To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Technetium-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and
millicuries indicated.

5.7 Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

5.8 Repeat the process until a volume of 19.0-cc has been assayed. The entire process must be completed within 10 minutes.

5.9 Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, the data may be graphed, with horizontal 5% error lines drawn above and below the chosen 'standard volume'.

5.10 If any correction factors are greater than 1.05, or less than 0.95, or if any data points lie outside the 5% error lines, it will be necessary to make a correction table or graph that will allow conversion from 'indicated value' to 'true activity'. If this is necessary, be sure to label the table or graph 'vial geometry dependence', and note the date of the test and the model number and serial number of the calibrator.

6. Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Institute of Standards and Technology (NIST) or by the supplier who has compared that source to a source that was calibrated by NIST. Certified sources are available from NIST and from many radioisotope suppliers. At least two sources with different principal photon energies (such as Cobalt-57, Cobalt-60, Cesium-137) should be used. One source should have a principal photon energy between 100keV and 500keV. If a Radium-226 source is used it should be at least 10 microcuries, other sources should be at least 50 microcuries. Consider using at least one reference source whose activity is within the range of activities normally assayed.

6.1 Assay a calibrated reference source at the appropriate setting (i.e., use the Cobalt-57 setting to assay Cobalt-57) and then remove the source and measure background.

Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for a total of three determinations.

6.2 Average the three determinations. The average value should be within the predetermined safety margin, which in this example is 5% of the certified activity of the reference source, mathematically corrected for decay.

6.3 Repeat the procedure for other calibrated reference sources.

6.4 If the average value does not agree, within 5%, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The dose calibrator should be repaired or replaced if the error exceeds 10%.

6.5 At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values with the accuracy data.

6.6 Put a sticker on the dose calibrator noting when the next accuracy test is due.

7. The individual performing the tests will sign or initial the records of geometry, linearity, and accuracy tests.

Appendix P:

Material Receipt and Accountability

Sample Model 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.
- Carriers should be instructed to deliver radioactive packages directly to the designated receiving area.

Sample Instructions to Personnel Involved in Material Receipt

Shipping and Receiving Personnel

During normal working hours, within 3 hours of receipt of any package of radioactive material, each package must be visually inspected for any signs of shipping damage, such as crushed or punctured containers or signs of dampness. Any suspected damage must be reported to the RSO immediately. Do not touch any package suspected of leaking. Request the person delivering the package, if still on site, to remain until monitored by the RSO.

Outside of normal working hours (e.g., nights, weekends, and holidays), deliveries may be made to a designated, secured storage area. These packages must be checked for contamination and external radiation levels within 3 hours after personnel arrive at the facility. They should not be allowed to remain in the designated storage area any longer than necessary, as they may be a source of exposure for pharmacy personnel.

Sample Model Procedure for Safely Opening Packages Containing Radioactive Materials

For packages received under the specific license, authorized individuals should 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 to ensure that the shipment does not exceed license possession limits;
- Monitor the external surfaces of a labeled package according to specifications in **Table 1**;
- Open the outer package (following supplier's directions if provided) and remove packing slip. Open inner package to verify contents, comparing requisition, packing slip, and label on the 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 anything other than the expected observation is identified, 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 VDH when removable radioactive surface contamination exceeds the limits of 22 disintegrations per minute per square centimeter (dpm/cm^2) averaged over 300 cm^2 (6600 dpm / 300 square centimeters); or external radiation levels exceed 2.0 mSv/hr (200 mrem/hr) at the surface.

Appendix Q:

General Topics for Safe Use of Radioisotopes and Model Emergency Procedures

General Topics for Safe Use of Radioisotopes

Each licensee using radioactive material should establish general rules for the safe use of the material so that workers know what is required. Typical instructions should include:

- Wear a laboratory coat or other protective clothing at all times when working with radioactive materials;
- Use syringe shields and vial shields when preparing and handling radioactive drugs;
- Measure all radiopharmaceuticals prior to transfer;
- Measure the molybdenum-99 content of each generator elution and do not transfer those radiopharmaceuticals for human medical use that will contain more than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m at the time of administration;
- Wear disposable gloves at all times when handling radioactive materials and change gloves frequently to minimize the spread of contamination;
- Before leaving the hot lab, monitor hands, shoes, and clothing for contamination in a low-background area, allowing sufficient time for instrument response;
- Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used;
- Do not store food, drink, or personal effects in areas where radioactive material is stored or used. Personal items brought into the restricted area (i.e., radios, compact discs, notepads, books, etc.) should be surveyed for contamination before removal from the area;
- Food and beverages used in the preparation of radiopharmaceuticals should be clearly labeled "*Not for personal consumption*" if stored with radioactive materials;
- 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 radioactive material when it is not under the constant surveillance and immediate control of the user(s).

Model Procedures for Handling Millicurie Quantities of Radioiodine

Due to the potential for significant intakes, due to volatility and accidental ingestion, and skin exposures (SDE) from contamination, licensees should establish specific procedures for the containment and handling of millicurie quantities of radioiodine, most commonly Iodine-131. The following guidance is the minimum that should be considered if the applicant intends to manipulate radioiodine:

- Manipulation of radioiodine (e.g., handling or compounding capsules, performing radioiodination, dispensing from bulk solution) should be conducted in an isolated area within the main hot lab of the pharmacy. This will aid in maintaining exposures ALARA and provide a means to isolate the area in the event of a spill;
- Radioiodine handling should only be performed inside a glovebox or fume hood. The ventilation for gloveboxes and fume hoods should be checked at least once every six months to ensure adequate airflow and confirm negative pressure with respect to the area around the glovebox or fume hood. Exhaust stacks for gloveboxes and fume hoods used for handling radioiodine should not be located near ventilation intakes to minimize the likelihood of recirculation to the pharmacy or to other tenants in a shared building;

- Gloveboxes and fume hoods must include appropriate filters (activated charcoal) to minimize effluents from radioiodine handling;
- Filters must be installed and used in accordance with the manufacturer's specifications (e.g., adequate air flow to ensure adequate residence time);
- Filters should be checked at installation and periodically, based on use, but not less than once per calendar quarter, to ensure continued efficiency;
- Air flow through fume hoods and gloveboxes should be confirmed before each use;
- Magna-helic sensors, if used, should be checked before each use of the glovebox or fume hood, to ensure minimum flow across the filter;
- Absorbent materials and dry chemical buffers, for use in the event of a spill, should be located near the area where millicurie quantities of radioiodine are handled;
- Additional protective clothing should be used when handling millicurie quantities of radioiodine. Personnel should be double gloved and use shoulder-length sleeve guards. The gloves and glove seals on gloveboxes should be checked periodically and replaced when needed; and
- All personnel handling greater than 500 millicuries of Iodine-131 in a year should be considered for bioassay. This is the threshold below which intakes over 1% of the annual limit on intake (ALI) are not likely and assumes no containment. When used in a properly operating fume hood, the threshold for consideration of the need for bioassay rises to 5 curies of Iodine-131. If used in a properly operating glovebox, with properly sealed glove ports and well maintained gloves, the threshold rises to 50 curies of Iodine-131 handled by one person per year. Pharmacies using gloveboxes that do not have sealed glove ports may not use the threshold indicated for that equipment, but may use the threshold for properly maintained fume hoods.

Model Procedures for Handling Events

Suggested Thresholds for Defining Minor Contamination Events, Minor Spills, and Major Spills

Licensees should establish clearly delineated thresholds for describing these types of events. Licensees should establish a graded response to emergencies, incorporating increasing formality of a response based on the potential risks posed by the events. No emergency procedure can anticipate every likely event; therefore, flexibility and judgment must be incorporated into such procedures. Most importantly, if licensee staff are not sure of the proper or expected response to any event, no matter how minor, they should be instructed to immediately cease further action, control access to the area, contact the RSO, and wait for instructions.

Although the following is only suggested guidance for establishing response thresholds, significant deviations in actual licensee emergency procedures should be clearly justified.

Minor Contamination Events

Those events typically identified through routine surveys that involve removable contamination levels greater than the licensee's action limit, but less than ten times the licensee's action limit. Minor contamination events can be easily decontaminated without the need for strict adherence to a step-by-step procedure. Such events require judgment on the part of the individual responding to determine the scope and extent of the contamination and to assess their ability to respond effectively. In order to prevent the spread of contamination, coworkers should be notified if decontamination of the area will be delayed. The RSO should be notified promptly of such events, either before, or immediately after, cleanup of the area. Isolated minor

contamination events may not require a formal root cause evaluation or extensive corrective action determinations; however, several events in the same location, involving the same individual, or during similar processes may warrant such in-depth evaluations and determinations.

Minor Spills

Those events typically identified at the time they occur (i.e., a dropped syringe or vial containing radioactive material) involving the release (spill) of radioactive material requiring a more formal adherence to a step-by-step procedure. Such events will usually involve millicurie quantities of material and have a potential for exposures to personnel or the public if not properly controlled and decontaminated. The upper limit for defining minor spills should not be more than five times the lowest annual limit on intake (ALI) of the material involved in the spill. Such a limit would include the following quantities of radioactive material:

1. Up to 400 millicuries of Technetium-99m;
2. Up to 150 microcuries of Iodine-131;
3. Up to 100 millicuries of Thallium-201; and
4. Up to 10 millicuries of Samarium-153.

Minor spills may warrant root cause evaluations and corrective action determinations, depending on the circumstances. The RSO should be notified immediately of such events so that decontamination procedures can be monitored. Minor spills involving quantities of radioactive material near the upper threshold may require more than one person to respond to assist in the cleanup, perform confirmation surveys, or monitor materials and personnel exiting the area.

Major Spills

Any spill involving a quantity of radioactive material in excess of the quantity defined for a minor spill is considered a major spill. Such spills have a greater potential for exposures to workers and the public, including the possibility of overexposure, if not properly contained. Individuals should never attempt to clean a major spill by themselves, or without the personal supervision and direction of the RSO. Major spills should generally be reported to VDH in accordance with the requirements of **12VAC5-481-1110**. Major spills may also require evaluations of intakes and skin doses, if personnel contamination is identified, as well as root cause evaluations and corrective action determinations. Qualified assistance should be sought immediately for those major spills that are beyond the licensee's capability to address.

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. Licensees should have emergency equipment readily available for handling spills. Spill response materials should include the following:
  - Disposable gloves;
  - Housekeeping gloves;
  - Disposable lab coats;
  - 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; and
- Pencil

Minor Contaminations and Spills of Liquids and Solids

- Instructions to Workers
  - These instructions apply to minor contamination events (less than 10 times the licensee's action limit) and minor spills of radioactive material. The response to each is similar; however, the response to minor contamination events need not be as formal as the response to spills involving millicurie quantities of radioactive material.
  - 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 other contaminated disposable material in the bag;
  - Resurvey the area. Check the area around the spill for contamination. Also check hands, clothing, and shoes for contamination; and
  - Report the incident to the Radiation Safety Officer (RSO) promptly.

- Reminders to RSO
  - Follow up on the decontamination activities and document the results;
  - As appropriate, determine cause and corrective actions needed; consider bioassays if radioactive material may have been ingested or inhaled; 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 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; and

- Follow the instructions of the RSO (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;
  - Skin contamination must be evaluated to determine potential exposures. Beta-emitting radionuclides have a high potential for resulting in shallow-dose exposures in excess of regulatory limits from small (microcurie) quantities of contamination;
  - Supervise decontamination activities and document the results. Documentation should include location and results of surveys and decontamination results;
  - Determine root cause and needed corrective actions; consider need for bioassays if radioactive material may have been ingested, inhaled, or absorbed; and
  - If necessary, notify VDH.

Minor Fires

- Instructions to Workers
  - If possible, 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 fire department and RSO (as instructed by RSO);
  - Once the fire is out, isolate the area to prevent the spread of possible contamination;
  - Ensure injured personnel received medical attention;
  - 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; and
  - Follow the instructions of the RSO (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO
  - Notify emergency medical personnel of any injured individuals who may be contaminated. Provide radiation safety assistance (e.g., monitoring) as needed or requested.
  - Supervise decontamination activities at the facility;
  - 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 contamination that was released by the perspiration;
  - Consult with fire safety officials to ensure that there is no likelihood of fire restarting;
  - Determine cause and needed corrective actions; consider need for bioassays if radioactive material may have been ingested or inhaled. 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;
  - Ensure injured personnel receive medical attention;
  - Upon arrival of firefighters, inform them where radioactive material are stored and where radioisotopes were being used; inform them of the present location of the radioactive 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;
  - Allow no one to return to work in the area unless approved by the RSO; and
  - Follow the instructions of the RSO (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).
- Reminders to RSO
  - Notify emergency medical personnel of any injured individuals who may be contaminated. Provide radiation safety assistance (e.g., monitoring) as needed or requested;
  - Coordinate activities 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 fire is extinguished;
  - Once the fire is extinguished, provide assistance to firefighters who may need to re-enter restricted areas to determine the extent of the damage to the radioactive material use or storage areas. To the extent practical, assist firefighters in maintaining their exposures ALARA if the fire resulted in a significant release of radioactive material or lost of shielding capability, such that excessive radiation levels (greater then 100 millirems per hour) are created;
  - Perform thorough contamination surveys of firefighters and their equipment before they leave the controlled area and decontaminate, if necessary;
  - Supervise decontamination activities;
  - Consider bioassays if radioactive material may have been ingested or inhaled. Document incident; and
  - If necessary, notify VDH

Note: Copies of emergency procedures should be provided to all users. A current copy of the emergency procedure should be posted in each area where radioactive material is used.

Appendix R:

Radiation Survey Procedures

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

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.
- Dose-rate surveys, at a minimum, should be performed in locations where members of the public could receive a total effective dose equivalent of 1 mSv (100 mrem) in a year, or the dose in any unrestricted area from external sources could exceed 0.02 mSv (2 mrem) in any one hour.
- Dose-rate surveys should be performed in a manner and frequency that is representative of the use of radioactive materials. At a minimum, these surveys should be conducted daily in areas of radioactive material use, where exposures to workers could reasonably occur (e.g. generator storage/elution and dose preparation stations). Other areas, where radiological conditions are not expected to change appreciably from day-to-day, should be surveyed weekly (e.g. radioactive waste storage areas).

Contamination Surveys

Licensees' contamination surveys should be sufficient to identify areas of contamination that might result in unacceptable levels of exposure 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 wipe tests, which should be analyzed using an appropriate counting instrument. Fixed contamination may be measured directly at the surface of the contamination with the appropriate instrument detector held at close proximity to the surface without direct contact. See **Table 5** in **Appendix J** for examples of appropriate instruments.

Contamination surveys should be performed:

- To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, or equipment;
- After any spill or contamination event;
- To evaluate contamination of users and the immediate work area at the end of each day when radioactive material is used;
- In unrestricted areas at frequencies consistent with the types and quantities of materials in use;
- In areas adjacent to restricted areas and in all areas through which radioactive materials are transferred and temporarily stored before shipment.

Contamination Survey Frequency

All areas where radioactive materials are eluted, prepared, assayed, dispensed, or packaged for transport should be surveyed daily. All other areas where radioactive materials are used or stored should be surveyed weekly.

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 8.**

Table 8: Recommended Action Levels in dpm/100 cm^2 for Removable Surface Contamination by Radiopharmaceuticals

	P-32, Se-75, Sr-85, Sr-89, In-111, I-123, I-125, I-131, Sm-153, Yb-169, Re-186, Au-198	Cr-51, Ga-67, Tc-99m, Tl-201
1. Unrestricted areas, personal clothing	200	2000
2. Restricted areas, protective clothing used only in restricted areas, skin	2000	20000

When equipment or facilities that are potentially contaminated are to be released for unrestricted use, the above table provides the maximum acceptable residual levels. To the extent practicable, it is appropriate to decontaminate 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 wipe testing of a relatively uniform area should be used to aid in comparing contamination at different times and places. A wipe taken from an area of approximately 100 cm^2 is acceptable to indicate levels of removable contamination.

Survey Record Requirements

Each survey report should include the following:

- Diagram of the area identifying specific locations surveyed (See **Figure 1**, located in **Item 13**);
- 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; and
- Corrective actions taken for elevated levels identified and results of resurveys.

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

Air Sampling

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.

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 air sampling, which are available at the NRC website, www.nrc.gov.

Air Stack Release Monitoring

Airborne radioactive effluents should be monitored at the release points (e.g., stack) to provide accurate measurements to estimate public exposure. Licensees should verify the performance of effluent monitoring systems by regular calibration of equipment and checks of filtration 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 VDH 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.

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'.

Radioiodine Monitoring

The handling of radioiodine requires additional surveys and monitoring. Such surveys and monitoring include:

- Routine surveys should be performed of air filters incorporated in fume hoods and gloveboxes to identify when filters should be exchanged prior to saturation;
- Routine surveys should be performed in the area where radioiodine is handled immediately following each use to identify elevated radiation and contamination levels; and
- Continuous monitoring of the air effluent should be performed during radioiodine use. In-line filters should be monitored periodically to determine actual effluents.

Sanitary Sewerage Release Monitoring

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

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 radionuclide;
- Sensitivity of the measurement technique; and
- Acceptable uncertainty in the estimate of intake and committed dose equivalent.

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

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

Routine Measurements

Routine measurements include baseline measurements, periodic measurements, and termination measurements. These measurements should be conducted to confirm that appropriate controls exist and to assess dose.

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 two hours should be excluded from the evaluation, since external exposure generally controls these radionuclides.

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 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:

- Presence of unusually high levels of facial and/or nasal contamination;
- 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; and
- Incidents that result in contamination of wounds or other skin absorption.

References:

1. NRC Regulatory Guide 4.20, 'Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors', dated December 1996.
2. NRC Regulatory Guide 8.9, Revision 1, 'Acceptable Concepts, Models, Equations , and Assumptions for a Bioassay Program', dated July 1993.
3. NRC Regulatory Guide 8.25, Revision 1, 'Air Sampling in the Workplace', dated June 1992.
4. NRC Regulatory Guide 8.37, 'ALARA Levels for Effluents from Materials Facilities', dated July 1993.
5. NRC NUREG-1400, 'Air Sampling in the Workplace', dated September 1993.
6. NRC NUREG/CR-4884, 'Interpretation of Bioassay Measurements', dated July 1987.
7. ANSI N13.1 (1969), 'Document to Sampling Airborne Radioactive Materials in Nuclear Facilities', dated 1991.
8. ANSI N42.18, 'Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents', 1991.

These can be accessed at the NRC's website, www.nrc.gov or by contacting VDH.

Appendix S:

Procedure for Return of Radioactive Wastes from Customers

Return only items that contained or contain radioactive materials supplied by the radiopharmacy (e.g., pharmacy-supplied syringes and vials and their contents). Most return shipments to radiopharmacies will qualify as excepted packages of limited quantity, in accordance with DOT requirements (**49 CFR 173.421**). For those packages containing radioactive material in excess of the limited quantity, customers should ensure that all applicable DOT requirements are met for the packages. This includes, but is not limited to, certification packaging (Type A), package marking and labeling, and shipping papers. For specific guidance on preparing these types of packages, please follow your in-house procedures for shipping radioactive material packages or contact the pharmacy for guidance.

Preparation of radioactive materials for return as excepted package of limited quantity:

- Ensure that the activities of material being returned are limited quantities as defined by DOT (see table below). Special attention should be given for the return of unused doses that may still contain significant activities of radionuclides. The amount of radioactivity in unused doses may necessitate that a syringe or vial be held for decay to reduce the activity to that permitted for shipment of limited quantities.
- Place the syringe or vial in the original, labeled, lead shield in which it was delivered; and
- Place shielded waste into the shipping package (e.g., padded briefcase or ammo box) in which it was delivered.

Note: Packages used to ship radioactive material to customers must meet the DOT package requirements for transport of limited quantities.

Preparation of package:

- Using a calibrated survey meter, measure the radiation levels at all points on the surface of the package to ensure that levels are less than or equal to 0.5 mrem/hr;
- Use contamination wipes on the surface of the package to ensure that the removable contamination does not exceed the limit specified in **49 CFR 173.443(a)** - 22 dpm/cm^2 over a 300 cm^2 area;
- Label the package as a "*Excepted Package - Limited Quantity of Material*"; and
- Seal the package so that it will be evident upon receipt whether the package accidentally opened during shipment.

Note: Shipping papers are not required when shipping limited quantities however, the statement specified in **49 CFR 173.422** ("*This package conforms to the conditions and limitations specified in **49 CFR 173.421** for radioactive material, excepted package-limited quantity of material, UN2910.*") must be included in, on, or otherwise provided with the shipment.

Limited Quantities (49 CFR 173.421) For Typical Radionuclides as Liquid Used by Radiopharmacies (49 CFR 173.425)

Table 9: Limited Quantity Values for Liquid Radioactive Material Packages

Radionuclide – Liquids	A2 Value	Limited Quantity Shipment (mCi) $A2 \times 10^{-4}$
Co-57	216	21.6
Co-58	27	2.7
Cr-51	811	81.1
Ga-67	162	16.2
I-123	162	16.2
I-125	54.1	5.41
I-131	13.5	1.35
In-111	54.1	5.41
Mo-99	20 (for domestic use)	2
P-32	8.11	0.81
Se-75	81.1	8.1
Sr-89	13.5	1.35
Tc-99m	216	21.6
Tl-201	270	27

Table 10: Limited Quantity Values for Gaseous Radioactive Material Packages

Radionuclide Uncompressed Gas	A2 Value (Ci)	Limited Quantity Shipment (mCi) $A2 \times 10^{-3}$
Xe-133 (uncompressed)	541	541

Table 11: Limited Quantity Values for Special Form Radioactive Material Packages

Radionuclide Solid – Special Form	A1 Value (Ci)	Limited Quantity Shipment (mCi) $A1 \times 10^{-3}$
Ir-192	27	27
Cs-137	54.1	54.1

The values above are derived from **49 CFR 173.423**, **Table 7**, and the Table of A1 and A2 values for radionuclides in **49 CFR 173.435**. If shipping more than one radionuclide in the same package, the limits in **49 CFR 173.433(d)** apply as follows:

- The sum of the ratios of the activity of each radionuclide divided by its respective A2 value must be less than, or equal to, one. For special form material, the sum of the ratios of the activities of each radionuclide divided by its respective A1 value must be less than, or equal to, one.

Procedure for Driver or Courier for Pick-up of Radioactive Waste from Customers

- Ensure that the shipping package is properly labeled "*Excepted Package - Limited Quantity of Material*";
- Ensure that the shipping package has been sealed; and
- Do not accept any package that is not properly labeled and sealed.

Procedure for Receipt and Opening of Packages from Customers Containing Radioactive Waste

- Place all returned packages in an identifiable location within the radiopharmacy;
- Put on disposable gloves;
- Monitor the package for removable contamination. If wipe tests indicate contamination levels greater than 22 dpm/cm^2 over a 300 cm^2 area, take the following actions:
  - Notify the customer and VDH; and
  - Survey the driver/courier who retrieved the waste and the vehicle used to transport the waste to the radiopharmacy.
  - Decontaminate the package or remove it from service for decay.
- Open the package and identify each nuclide in the shielded containers.
- Dispose of radioactive waste into the appropriate container for the half-life of the nuclide being disposed, in accordance with the radiopharmacy's procedures for disposal of waste by decay-in-storage.
- Survey the dose shields for contamination with a low-level survey meter. Any dose shield that indicates an activity exceeding background should be decontaminated or removed from service.

Appendix T:

VDH Incident Notifications

Table 12: Typical Notifications Required for Radiopharmacy Licensees

Event	Telephone Notification	Written Report	Regulatory Requirement
Theft or loss of material	Immediate	30 days	**12VAC5-481-1090**
Whole body dose greater than 0.25 Sv (25 rems)	Immediate	30 days	**12VAC5-481-1100**
Extremity dose greater than 2.5 Sv (250 rems)	Immediate	30 days	**12VAC5-481-1100**
Intake of five times the annual limit on intake	Immediate	30 days	**12VAC5-481-1100**
Removable contamination exceeding the limits of **12VAC5-481-3080** (beta/gamma/low toxicity alpha – 22 dpm/cm^2; all other alpha – 2.2 dpm/cm^2)	Immediate	30 days	**12VAC5-481-900**
External radiation levels exceeding the limits of **12VAC5-481-3080** (any point on the surface – 2 mSv/hr (200 mrem/hr))	Immediate	None	**12VAC5-481-900**
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	**12VAC5-481-1100**
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	**12VAC5-481-1100**
Intake one annual limit on intake	24 hours	30 days	**12VAC5-481-1100**
Occupational dose greater than the applicable limit in **12VAC5-481-640**	None	30 days	**12VAC5-481-1110**
Dose to individual member of public greater than 1 mSv (100 mrems)	None	30 days	**12VAC5-481-1110**
Filing petition for bankruptcy under 11 U.S.C.	None	Immediately after filing petition	**12VAC5-481-500**
Expiration of license	None	60 days	**12VAC5-481-500**
Decision to permanently cease licensed activities at **entire site**	None	60 days	**12VAC5-481-510**
Decision to permanently cease licensed activities in any **separate building or outdoor area** that is unsuitable for release for unrestricted use	None	60 days	**12VAC5-481-510**

Event	Telephone Notification	Written Report	Regulatory Requirement
No principal activities conducted for 24 months **at the entire site**	None	60 days	**12VAC5-481-510**
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	Immediate	30 days	**12VAC5-481-1100**
An unplanned contamination event involving greater than 5 times the ALI, and half-life greater than 24 hours requiring access to be restricted for more than 24 hours	24 hours	30 days	**12VAC5-481-1100**
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	**12VAC5-481-1100**
Unplanned fire or explosion that affects the integrity of any radioactive material or device, container, or equipment with radioactive material	24 hours	30 days	**12VAC5-481-1100**

Note: Telephone notifications shall be made to VDH at (804) 864-8150 (7:45 a.m. until 4:30 p.m.) and in an emergency to (800) 468-8892 or (804) 674-2400 (after hours).

Commonwealth of Virginia
Radiation Protection Regulatory Guide

Guidance for Well Logging, Tracer, and Field Flood Study

EPI-720 J

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

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

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

This VAREG, 'Guidance for Well Logging, Tracer, and Field Flood Study', has been developed to streamline the application process for a Well Logging, Tracer, and Field Flood Study license. A copy of the VDH form, 'Application for a Radioactive Material License Authorizing the Use of Material in Well Logging, Tracer, and Field Flood Study', is located in **Appendix A** of this guide.

Appendix F through V provide examples, models, and additional information that can be used when completing the application.

It typically takes 60-90 days for a license to be processed and issued if the application is complete. When submitting the application be sure to include the appropriate application fee listed in **12VAC5-491**.

In summary, the applicant will need to do the following to submit an application for a well logging, tracer, or field flood study license:

- Use this regulatory guide to prepare the VDH form, 'Application for a Radioactive Material License Authorizing the Use of Material in Well Logging, Tracer, and Field Flood Study' (**Appendix A**).
- Complete the VDH form, 'Application for a Radioactive Material License Authorizing the Use of Material in Well Logging, Tracer, and Field Flood Study' (**Appendix A**). See 'Contents of Application' of the guide for additional information.
- Include any additional attachments:
    - All supplemental pages should be on 8 ½" x 11" paper.
    - Please identify all attachments with the applicant's name and license number (if a renewal).
- Avoid submitting proprietary information unless it is absolutely necessary;
- Submit an original signed application along with attachments (if any).
- Submit the application fee (for new licenses only).
- Retain one copy of the licensee application and attachments (if any) for your future reference. You will need this information because the license will require that radioactive material be possessed and used in accordance with statements, representation, and procedures provided in the application and supporting documentation.

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

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ABBREVIATIONS

ALARA	As Low As is Reasonably Achievable
ALI	Annual Limit on Intakes
ANSI	American National Standards Institute
bkg	Background
BPR	Business Process Redesign
Bq	Becquerel
cc	centimeter cubed
CDE	Committed Dose Equivalent
CEDE	Committed Effective Dose Equivalent
Ci	Curie
CFR	Code of Federal Regulations
cm^2	centimeter squared
cpm	counts per minute
C/kg	Coulombs/Kilogram
cpm	Counts Per Minute
DFP	Decommissioning Funding Plan
DIS	Decay-In-Storage
DOE	United States Department of Energy
DOT	United States Department of Transportation
dpm	Disintegrations Per Minute
DTS	Drill-To-Stop
EA	Environmental Assessment
ECS	Energy Compensation Source
EDE	Effective Dose Equivalent
EPA	United States Environmental Protection Agency
F/A	Financial Assurance
FDA	United States Food and Drug Administration
FR	Federal Register
GM	Geiger-Mueller
GBq	Gigabecquerel
IN	Information Notice
LLW	Low Level Waste
LSA	Low Specific Activity
LWD	Logging While Drilling
MBq	Megabecquerel
MC	Manual Chapter
MCi	millicurie
mGy	Milligray
mR	Milliroentgen
mrem	Millirem
mSv	Millisievert
MWD	Measurement While Drilling
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NMSS	Office of Nuclear Material Safety and Safeguards
NORM	Naturally-Occurring Radioactive Material
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OSL	Optically Stimulated Luminescence

QA	Quality Assurance
R	Roentgen
RG	Regulatory Guide
RQ	Reportable Quantities
RSO	Radiation Safety Officer
SDE	Shallow Dose Equivalent
SI	International System of Units (abbreviated SI from the French Le Systeme Internationale d'Unites)
SSD	Sealed Source and Device
SSDR	Sealed Source and Device Registration
std	Standard
Sv	Sievert
T1/2	Half-life
TAR	Technical Assistance Request
TEDE	Total Effective Dose Equivalent
TI	Transportation Index
TLD	Thermoluminescent Dosimeters
USASI	United States of America Standards Institute
USC	United States Code
USDA	United States Department of Agriculture
VDH	Virginia Department of Health
μCi	microcurie
%	percent

PURPOSE OF GUIDE

This document provides guidance to an applicant in preparing a license application for well logging, tracer, and field flood study. It also provides guidance on VDH's criteria for evaluating a well logging, tracer and field flood study license application. It is not intended to address the commercial aspects of manufacturing, distribution, and service of sources in devices. Byproduct material, depleted uranium, and special nuclear material, as defined in **12VAC5-481-10**, are used for a variety of purposes to include well logging and tracer applications involving both single or multiple well bores; conventional well logging and tracer operations; and, in some cases, research and development. Examples include the following applications:

- Sealed sources are used in cased and uncased boreholes
- Tracer materials are used in single well applications
- Tracer materials are used in multiple well applications (field flood study) for enhanced recovery of oil and gas wells
- Sealed sources are used for calibration of applicant's survey instruments and well logging tools
- Sealed sources and tracer materials are used in the research and development of new techniques and equipment.

This guide identifies the information needed to complete VDH form 'Application for a Radioactive Material License Authorizing the Use of Material in Well Logging, Tracer, and Field Flood Study' (**Appendix A**).

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

- **Rule** - references the requirements from **12VAC5-481 'Virginia Radiation Protection Regulations'** applicable to the item;
- **Criteria** - outlines the criteria used to judge the adequacy of the applicant's response;
- **Discussion** - provides additional information on the topic sufficient to meet the needs of most
  readers, 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 the agency's guidelines. Submission of incomplete or inadequate information will result in delays in the approval process for the license. Additional information will be requested when necessary to ensure that an adequate radiation safety program has been established. Such requests for additional information will delay completion of the application's review and may be avoided by a thorough study of the rule and these instructions prior to submitting the application.

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

In this guide, "dose" or "radiation dose" means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent (TEDE). These terms are defined in the **12VAC5-481-10.** Rem and Sievert (Sv), its SI equivalent (1 rem = 0.01 Sv), are used to describe units of radiation exposure or dose. These units are used because **12VAC5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation',** sets dose limits in terms of rem, not rad or roentgen. 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 14. The VAREG shows the requirements in terms of the **12VAC5-481 'Virginia Radiation Protection Regulations'** and provides a user-friendly format to assist with the preparation of a well logging, tracer and field flood study license application.

LICENSES

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

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

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

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

12VAC5-481-630, Radiation protection programs, states that *"each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities"* and *"the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are...ALARA."* This section also requires that licensees review the content of the radiation protection program and its implementation annually.

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

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

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

WHO REGULATES FACTILITIES 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 in order to determine whether the Nuclear Regulatory Commission (NRC) or VDH has regulatory authority. The NRC has regulatory authority only over land determined to be "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 contact for the federal agency controlling the site (e.g., contract officer, base environmental health officer, district office staff) to help determine the jurisdictional status of the land and to provide the information in writing, so that licensees can comply with NRC or VDH regulatory requirements, as appropriate. The following table lists examples of regulatory authority.

Table 1: Who Regulates Activity?

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

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

MANAGEMENT RESPONSIBILITY

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

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

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

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

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

APPLICABLE RULE

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

The following parts of **12VAC5-481, 'Virginia Radiation Protection Regulations'** contain regulations applicable to well logging, tracer, and field flood study 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; Inspections'
- Part XIII 'Transportation of Radioactive Material'
- Part XIV 'Radiation Safety Requirements for Wireline Service Operations and Subsurface Tracer Studies'

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

HOW TO FILE

Applicants for a materials license should do the following:

- Be sure to use the most recent guidance from VDH in preparing an application.
- Complete VDH form, 'Application for a Radioactive Material License Authorizing the Use of Material in Well Logging, Tracer, and Field Flood Study' (**Appendix A**).
- For each separate sheet that is 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 8-1/2 x 11 inch paper.
- Avoid submitting proprietary information unless it is necessary
- Submit an original, signed application.
- Retain one copy of the license application for future reference.

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

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

WHERE TO FILE

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

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

LICENSE FEES

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

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

Direct all questions about VDH's fees or completion of **Item 13** of VDH form, 'Application for a Radioactive Material License Authorizing the Use of Material in Well Logging, Tracer, and Field Flood Study' (**Appendix A**) to: Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219 or call (804) 864-8150.

CONTENTS OF AN APPLICATION

Item 1: Type of Application

On the application, check the appropriate box and, if appropriate, note the license number.

Response from Applicant:

Item 1 Type Of Application (Check one box)
☐ New License ☐ Renewal License Number _____

Item 2: Name and Mailing Address of Applicant

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

Notify the agency of changes in mailing address.

Response from Applicant:

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

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

Timely Notification of Transfer of Control

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

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

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

- Radioactive materials are possessed, used, or controlled only by persons who have valid licenses issued by VDH, NRC, or another Agreement State;
- 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 the disposition of records and licensed materials;
- Public health and safety are not compromised by the use of such materials.

Response from Applicant: None at time of application.

Notification of Bankruptcy Proceedings

Rule: 12VAC5-481-500

Criteria: Immediately following filing of voluntary or involuntary petition for bankruptcy, 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 totally responsible
for all regulatory requirements. VDH needs to know when a licensee is in bankruptcy proceedings in order to ensure the material and facilities are under control, in accountability, and do not cause any public health and safety concerns. VDH shares its findings with other entities (i.e., trustees, etc) so that health and safety issues can be resolved prior to completion of bankruptcy proceedings.

VDH must be notified immediately once a petition is filed for bankruptcy.

Response from Applicant: None at time of application.

Item 3: Person to Contact Regarding Application

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

Discussion: This is typically the proposed Radiation Safety Officer or a knowledgeable management official, 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 the contact person's telephone number changes so that the agency can contact the applicant or licensee in the future with questions, concerns, or information. This notice is 'for information only' and does not require a license amendment or a fee.

Response from Applicant:

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

Item 4: Location of Radioactive Material

Rule: 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-3151, 12VAC5-481-3180, 12VAC5-481-3350, 12VAC5-481-3360

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

Discussion: Specify the street address, city, and state or other descriptive address (e.g., on Highway 17,
5 miles east of the intersection of Highway 10 and State Route 234, Anytown, VA) for each facility at which licensed material will be used, stored, or dispatched, and any field stations. Field stations are locations where licensed materials are stored or used and equipment is dispatched to temporary job sites. If devices will not be stored at a dispatch or field station, indicate this. The applicant should indicate whether or not these facilities will be used for use and/or storage of devices. A Post Office Box is not acceptable.

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).

Response from Applicant:

Item 4 Location of Radioactive Material (Do not use Post Office Box): (Attach additional pages if necessary)		
☐ Used ☐ Stored ☐ Used and Stored	Address: , -	Telephone Number (Include area code): ( ) - x
☐ Used ☐ Stored ☐ Used and Stored	Address: , -	Telephone Number (Include area code): ( ) - x
☐ Used ☐ Stored ☐ Used and Stored	Address: , -	Telephone Number (Include area code): ( ) - x

Are devices going to be used and/or stored at field stations? ☐ Yes ☐ No

Are devices going to be used and/or stored at temporary jobsites?: ☐ Yes ☐ No

If yes, check the following boxes:

- ☐ We will perform and maintain documentation of radiation surveys to ensure that radiation levels are less than 2 mR in any one hour and 100 mR/yr at all temporary job site storage locations.
- ☐ We will store the device at the temporary job site in a locked room, trailer, or other secure location to prevent unauthorized removal of the device.
- ☐ We will minimize exposures for occupational and non-occupational workers when selecting storage location.
- ☐ We will limit storage at a temporary job site to 180 days per calendar year.

Note: As discussed later under "Financial Assurance and Record Keeping for Decommissioning," licensees do need to maintain permanent records on where licensed material was used or stored while the license was in force. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated).

Item 5: Radiation Safety Officer (RSO)

Rule: 12VAC5-481-450 A, 12VAC5-481-500, 12VAC5-481-3151

Criteria: RSOs and potential designees are responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures, and must have adequate training and experience.

Discussion: The person responsible for the radiation protection program is called the RSO. The agency believes the RSO is the key to overseeing and ensuring safe operation of the licensee's well logging, tracer, or field flood study program. The RSO needs independent authority to stop operations that he or she considers unsafe and have sufficient time and commitment from management to fulfill certain duties and responsibilities that ensure that radioactive materials are used in a safe manner.

The RSO may delegate certain day-to-day tasks of the radiation protection program to other responsible individuals (potential designees). For example, a large well logging firm with multiple field stations and/or temporary job sites may appoint individuals designated as 'site RSOs' who assist the RSO and are responsible for the day-to-day activities at the field stations and/or temporary job sites. Licensees may also appoint other individuals who may 'step-in' as an emergency contact when the RSO is unavailable. The potential designees do not need to meet the required RSO qualifications; however, these individuals should be qualified and experienced with adequate knowledge of the activities to which they are assigned. Applicants do not have to identify other responsible individuals if day-to-day tasks, etc. will not be delegated.

Table 2. Radiation Safety Officer Duties and Authorities

Radiation Safety Officer
Duties and Authorities
1. Establish and oversee all operating, emergency, and ALARA procedures and review them regularly.
2. Oversee proper disposal of all material including transportation of the material according to VDH and DOT requirements.
3. Ensure required inventories, leak tests, etc are conducted and the records are recorded and maintained.
4. Ensure personnel are trained as required.
5. Operations are conducted safely and corrective actions are implemented, when necessary, including terminating operations.
6. Make certain all use and maintenance is performed and operations and equipment are used properly.
7. Perform annual audit and notify appropriate parties if any item is found to be not in compliance with VDH rule.
8. Maintain records and calibration of all survey instruments and determine each for proper operation.
9. Preserve accountability of all sources and devices while in field and in the office.
10. Be prepared to monitor any emergency event including loss of a source downhole or possible rupture.
Above all, the RSO is the key to maintaining the radiation safety of the operations to the workers, the public, and the environment.

Typical RSO duties are listed in **Table 2** and **Appendix K**. The agency requires the name of the RSO on the license to ensure that licensee management has always identified a responsible, qualified person and that the named individual knows of his or her designation as RSO. Provide the agency with a copy of an organizational chart showing the RSO and other designated responsible individuals, to demonstrate that he or she has sufficient independence and direct communication with responsible management officials. Also, show in the organizational chart the position of the individual who signs the application in **Item 14** of the VDH form, 'Application for a Radioactive Material License Authorizing the Use of Material in Well Logging, Tracer, and Field Flood Study' (**Appendix A**).

To be considered eligible for the RSO position, the applicant must submit for review the specific training and experience of the proposed RSO and detail his or her duties and responsibilities. The proposed RSO should have had a minimum of 1 year of actual experience as a logging supervisor. The RSO is expected to coordinate the safe use of licensed materials and to ensure compliance with the applicable requirements of **12VAC5-481, 'Virginia Radiation Protection Regulations'**. The RSO should possess a thorough knowledge of management policies, company administrative and operating procedures, and safety procedures related to protection against radiation exposures.

Response from Applicant:

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

☐ 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.

NAME: _____ TELEPHONE NUMBER: _____ (Include area code)

AND

☐ We will demonstrate that the RSO has sufficient independence and direct communication with responsible management officials by providing a copy of an organizational chart by position and will confirm that the RSO has day-to-day oversight of the radiation safety activities.

AND EITHER

☐ We have included documentation showing the RSO's qualifications and experience

OR

☐ We will provide alternative information demonstrating that the proposed RSO is qualified by training and experience (e.g.listed by name as an authorized user or the RSO on an VDH, NRC, or another Agreement State license that requires a radiation safety program of comparable size and scope) including documentation to show that the RSO has obtained formal training in the establishment and maintenance of a radiation protection program.

Note: It is important to notify the agency and obtain a license amendment prior to making changes in the designation of the RSO responsible for the radiation safety program.

Item 6: Training for Logging Supervisors and Logging Assistants, and Tracer/Field Flood Study Users

Rule: 12VAC5-481-30, 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-2260, 12VAC5-481-2270, 12VAC5-481-2280, 12VAC5-481-3151, 12VAC, 5-481-3270

Criteria: Well logging supervisors and well logging assistants must have adequate training and experience as outlined in **12VAC5-481-450 A, 12VAC5-481-2270,** and **12VAC5-481-3270.** Although persons engaged in field flood studies operations are not specifically addressed in **12VAC5-481 'Virginia Radiation Protection Regulations', Part XIV, 'Radiation Safety Requirements for Wireline Service Operations and Subsurface Tracer Studies'**, the agency will accept classroom training for tracer studies to be an appropriate guide for individuals engaged in field flood studies.

Discussion: A logging supervisor is a person who performs or personally supervises well logging operations, tracer/field flood study applications and is responsible for ensuring compliance with VDH regulations and the safe use of radioactive materials. A logging assistant is an individual, who under the direct supervision and in the physical presence of the logging supervisor, uses well logging equipment (sealed sources containing byproduct material, related handling tools, unsealed sources of byproduct material, well logging devices, and radiation survey instruments) in performing well logging operations.
Didactic training and testing requirements, performance requirements, annual refresher training, and annual audit requirements for logging supervisors and logging assistants are outlined in **12VAC5-481-3270**. Refer to **Appendix L** as an aid in determining the specific training requirements for logging supervisors, logging assistants, and individuals authorized to conduct field flood study/tracer applications. The applicant must submit a description of its training program for logging supervisors, logging assistants, and/or individuals authorized to conduct field flood study applications. Because **12VAC5-481-3270** contains different requirements for logging supervisors and logging assistants, applicants must include training programs for each category. When describing the training programs for these positions, include the sequence of events from the time of hiring through the designation of individuals as logging supervisors or logging assistants. Experienced logging supervisors who have worked for another well logging, tracer, or field flood study licensee should receive formal instruction similar to that given to prospective logging assistants.

Instructors who provide classroom training to individuals in the principles of radiation and radiation safety should have knowledge and understanding of these principles beyond those obtainable in a course similar to the one given to prospective logging supervisors. Individuals who provide instruction in the hands-on use of well logging and handling equipment should be qualified logging supervisors with at least 1 year of experience in performing well logging operations, or should possess a thorough understanding of the operation of well logging and handling equipment (e.g., a manufacturer's service representative).

An internal inspection program (audit) of the job performance of each logging supervisor and logging assistant ensures that the VDH regulations, license requirements, and the licensee's operating and emergency procedures are followed. The audit must include observation of the performance of each logging supervisor and logging assistant during an actual well logging operation at intervals not to exceed 12 months. If a logging supervisor or logging assistant has not participated in a well logging operation for more than 12 months since the last inspection, the individual must be inspected the first time he or she engages in well logging operations.

Response from Applicant:

Item 6 Training For Logging Supervisors, Logging Assistants, and Tracer/Field Flood Study Users

(Check box and attach requested information)

☐ We will submit an outline of the training to be given to prospective logging supervisors and logging assistants and have enclosed our training procedures given to experienced logging supervisors. We have also submitted a typical examination given, the correct answers to the questions, and the passing grade.

AND

☐ We have included the qualifications of our instructors and their experience with well logging activities or have included the course title, name, course outline (if available), address, and telephone number of the company who will provide training.

AND

☐ We have submitted a description of the field examination given to prospective logging supervisors and assistants.

AND

☐ We have submitted an description of our program including the annual refresher training with the topics and how they will be covered, and the inspection of each logging supervisor and logging assistants job performance, as described in **12VAC5-481-3151**.

Item 7: Radioactive Material

Rule: 12VAC5-481-10, 12VAC5-481-400 B & H, 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-1151, 12VAC5-481-3151, 12VAC5-481-3180, 12VAC5-481-3190, 12VAC5-481-3240, 12VAC5-481-3241, 12VAC5-481-3250, 12VAC5-481-3300, 12VAC5-481-3310, 12VAC5-481-3320, 12VAC5-481-3430; 12VAC5-481-3740

Criteria: An application for a license will be approved if the requirements of **12VAC5-481-440, 12VAC5-481-450,** and **12VAC5-481-3151** 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.

Any sealed source used for well logging that contains more than 3.7 MBq (100 microcuries) of byproduct or special nuclear material and is used downhole in well bores of gas wells, oil wells, or in mineral deposits, must satisfy one of the following criteria:

- Sealed sources that were manufactured before July 14, 1989, may use either the design and performance criteria from the United States of America Standards Institute (USASI) N5 10-1968 or the criteria specified in **12VAC5-481-3240**. The use of the USASI N5 10-1968 standard is based on an NRC Notice of Generic Exemption, a copy of the referenced generic exemption letter is included in **Appendix J**.
- Sealed sources are required to satisfy the requirements of **12VAC5-481-3240**.

The primary difference between the two standards is that the vibration requirement in **12VAC5-481-3240** is not included in the USASI standard. This vibration test was included to ensure consistency between the United States standard and international standards.

Discussion: Applicants should list each requested radioisotope by its element name and mass number (e.g., cesium-137), specify whether the material will be acquired and used in unsealed or sealed form, and list the maximum amount requested. See **Appendix E** for a sample license.

Note: Additional safety equipment and precautions are required when handling and using unsealed free-form volatile radioactive materials. (Volatile means that a liquid becomes a gas at a relatively low temperature when the sealed container within which the liquid is stored is left open to the environment.) Applicants requesting an authorization to use volatile radioactive material must provide appropriate facilities, handling equipment, and radiation safety procedures for using such material.

Possession limits should be specified in megabecquerels (MBq) (millicuries (mCi)) or gigabecquerels (GBq) (curies (Ci)) for each radioisotope. Applicants should include in the possession limits requested the total estimated inventory, including licensed material in storage and maintained as radioactive waste. The requested possession limits for any radioisotope should be commensurate with the applicant's needs and facilities for safe handling. Applicants, when establishing their possession limits for radioactive materials with half lives greater than 120 days, should review the requirements for submitting a certification for financial assurance for decommissioning, see **Appendix I**.

If a dose evaluation indicates, due to a release of radioactive materials, that the potential dose to a person off-site would exceed 0.01 sieverts (Sv) (1 rem) effective dose equivalent or 0.05 Sv (5 rems) to the thyroid, an emergency plan for responding to a release shall be included with the application. For Iodine-131, the quantity requiring an emergency plan is 370 GBq (10 curies).

Consult with the proposed supplier, manufacturer, or distributor to ensure that requested sources and devices, where applicable, are compatible with and conform to the sealed source and device designations as registered. 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 may want to get a copy of the certificate and review it or discuss it with the manufacturer.

Sealed Sources

NRC or another Agreement State performs a safety evaluation of sealed sources before authorizing a manufacturer or distributor to distribute sources to specific licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) Registration Certificate. Some examples of sealed sources used in well logging applications are shown in **Figure 1**.

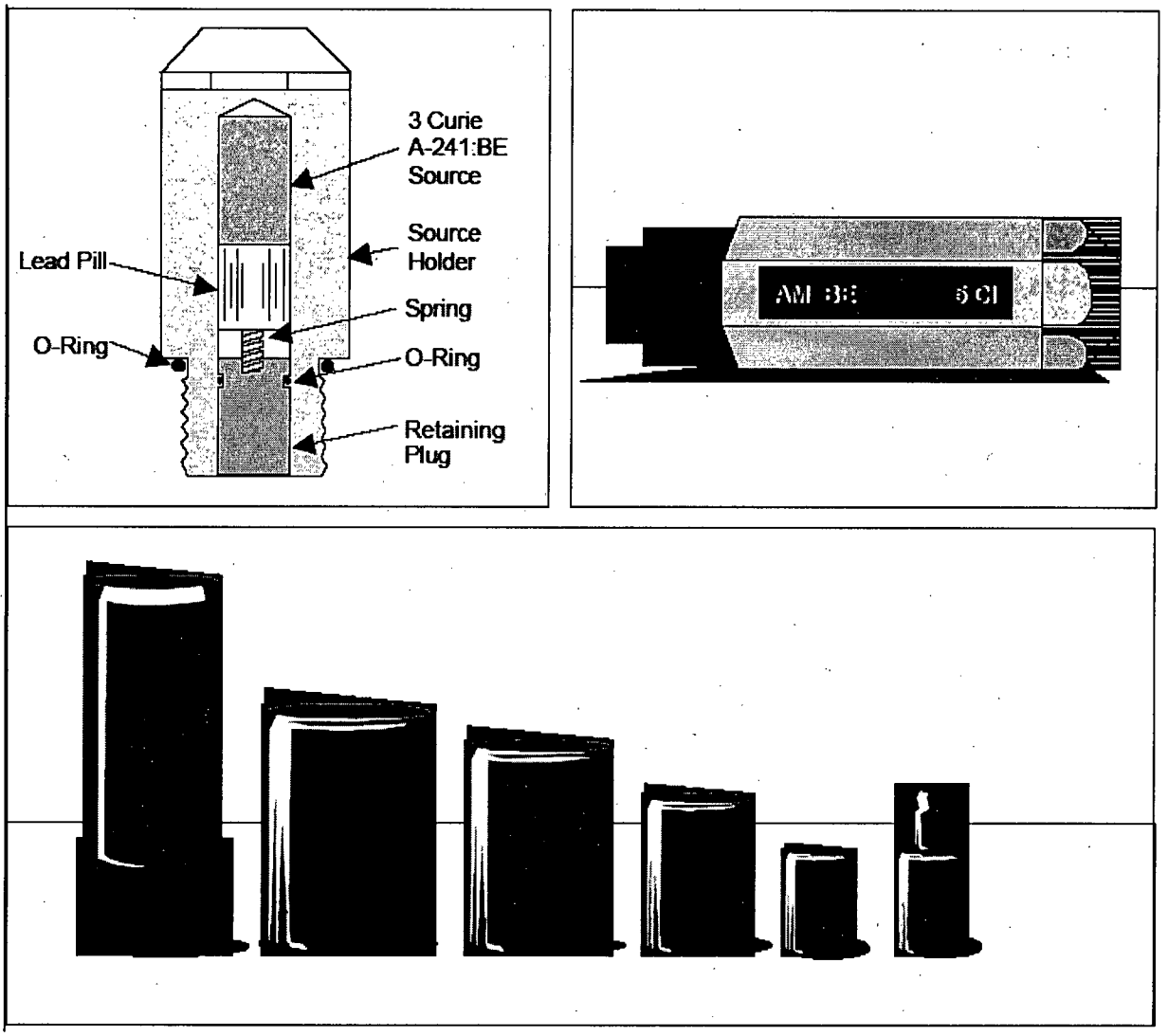


Figure 1. Examples of Sealed Sources Used in Well Logging Operations.

Applicants must provide the manufacturer's name and model number for each requested sealed source. This information is necessary to ensure that each sealed source requested in the application is included in an SSD Registration Certificate, approved under the provisions granted by **12VAC5-481-3240**, or is identified on an VDH license and authorized for well logging. Applicants should consult with the proposed suppliers or vendors to ensure that the sealed sources and their uses for them, and if applicable, devices and other associated equipment, are in accordance with Registration Certificates. Applicants are encouraged to obtain copies of applicable SSD Registration Certificates for future reference.

For sealed sources used for well logging applications, only authorized possession of individual sealed sources are approved for well logging. To allow flexibility, it is necessary to get authorization for specific sealed source/well logging tool combinations. Consult with the manufacturer of the sealed sources before using associated equipment (e.g., well logging tools, transport containers, handling tools, etc) to ensure that the associated equipment selected is compatible with sealed sources requested in the application.

A safety evaluation of sealed sources and devices is performed by NRC or another Agreement State before authorizing a manufacturer (or distributor) to distribute them to specific licensees. The safety evaluation is documented in a SSD Registration Certificate. SSD Registration Certificates contain sections on "*Conditions of Normal Use*" and "*Limitation and Other Considerations of Use*". These sections may include limitations derived from conditions imposed by the manufacturer or distributor, by particular conditions of use that would reduce radiation safety of the device, or by circumstances unique to the sealed source or device. Except as specifically approved by VDH, licensees are required to use the sealed source and devices according to their respective SSD Registration Certificates. Information on SSD Registration Certificates may be obtained through the agency, if necessary. Applicants must provide the manufacturer's name and model number for each requested sealed source and device (e.g., instrument calibrator) so that the agency can verify that each, when applicable, has been evaluated in an SSD Registration Certificate.

Tracer Materials

Each authorized radioisotope tracer will be listed on the license by its element name, chemical and/or physical form, and total possession limit. **Table 3** identifies the types of byproduct material used in tracer and field flood study applications covered by this report.

The following definitions are provided to clarify single and multiple well tracer operations addressed in this report:

- **Tracer Materials:** Radioactive isotopes in liquid, solid, or gas form that are injected into single well bores or underground reservoirs to monitor the movement of fluids or gases. Tracer studies involve a single well and require the use of an electronic well logging tool to detect the radioactive isotopes injected into the well.
- **Field Flood Studies or Enhanced Oil and Gas Recovery Studies:** Tracer studies involving multiple wells where one or more radioactive isotopes are injected and multiple oil or gas samples containing radioactive material are collected from each of the wells to determine the direction and rate of flow through the formation. Field flood tracer operations would not normally involve the use of an electronic well logging tool to detect the radioactive isotopes in the well.
- **Labeled Frac Sands:** Radioactive isotope(s) in liquid or solid forms that is (are) chemically bonded to glass and/or resin beads and injected into a single well in a density-controlled solution. Frac sand operations require the use of an electronic well logging tool to assess the amount of radioactive isotope(s) remaining in the underground reservoir formation.

Table 3. Types of Radioactive Materials Used in Field Flood Studies and Single Well Tracer Operations

Field Flood or Enhanced Oil and Gas Recovery Study Applications Tracers Used in Multiple Wells	
Gas	H-3, Kr-85, C-14, Br-82
Liquid	H-3, Na-22, S-35, Ca-45, Co-60, Ni-63, Zn-65, Sr-85, Sc-46, Sr-90, Ag-110m, I-125, I-131, La-140, Ir-192
Well Logging Tracer Applications Tracers Used in a Single Well	
Gas	Br-82, I-131, I-125
Liquid	Fe-59, I-125, I-131, Sb-124, Au-198, Ag-110m
Labeled Frac Sand	Sc-46, Br-82, Ag-110m, Sb-124, Ir-192

Applicant must provide emergency plan, if required. Emergency plans are not routinely required for tracer materials with half-lives of less than 120 days and for quantities authorized in well logging and tracer licenses. Applicants should refer to **12VAC5-481-3740** to determine the quantities of radioactive material requiring an emergency plan for responding to a release.

See the table in **Appendix C** to support the request for byproduct, source, or special nuclear material used in well logging operations and radioactive materials used for purposes other than well logging, e.g., radiation survey instrument calibrators.

Response from Applicant:

Item 7 Radioactive Material (Attach additional pages if necessary) Include sealed sources activity greater then 3.7 MBq (100 μCi)	
Element and mass number	Sealed source manufacturer and model number
Maximum activity per source	Source changer manufacturer and model number
Are unsealed tracer materials used? ☐ Yes (complete below information) ☐ No	
Element name and mass number	Chemical/physical form
Maximum activity per tracer material Maximum amount per study by physical/chemical form	If volatile, anticipated rate of volatility or dispersion Intended use
Are energy compensation sources used? ☐ Yes (complete below information) ☐ No	
Element name and mass number	Manufacturer's name and model number

Item 7.1: Purpose(s) for Which Licensed Material will be Used

Rule: 12VAC5-481-450, 12VAC5-481-480, 12VAC5-481-3151, 12VAC5-481-3240, 12VAC5-481-3250, 12VAC5-481-3261, 12VAC5-481-3280, 12VAC5-481-3320

Criteria: Radioisotopes and sealed sources requested in the application must be used for purposes authorized by **12VAC5-481, 'Virginia Radiation Protection Regulations'**. The licensee must specify the purpose for which each radioisotope or sealed source listed in **Item 7** is to be used, as well as specifying the type of wells in which each type of material will be used (e.g., oil, gas, mineral, geophysical, etc.). In addition, the licensee should describe the type of mineral or geophysical logging to be conducted (e.g., coal, salt domes, etc). Sealed sources used in well logging devices should be used only for the purposes for which they were designed, in accordance with the manufacturer's written recommendations and instructions, as specified in an approved SSD Registration Certificate, and as authorized on an VDH license. The licensee shall specify the manufacturer and model number of each device.

Discussion: The applicant's request to use sealed sources and radioisotopes in well logging, tracer, and field flood studies should clearly specify the purpose for which each type of material will be used. Applicants should include a description that is sufficiently detailed to allow a determination for the potential for exposure to occupationally exposed individuals and/or members of the public.

Note: Traditionally, only federal or state authorities have been authorized to conduct logging in potable water wells in fresh water aquifers. Approval to conduct these operations requires that applicants justify the need and to provide assurance that sealed sources, in case of accidental loss in a potable water zone, could be recovered.

Applicants requesting authorization to perform any of the hazardous operations listed below should clearly indicate their intent and provide specific instructions for conducting such activities in their operating and emergency procedures:

- Removing a sealed source from a source holder of a logging tool and maintenance on sealed sources or holders
- Using destructive techniques to remove a stuck sealed source from a source holder
- Opening, repairing, or modifying any sealed source
- Knowingly injecting licensed radioactive tracer material into a fresh water aquifer
- Using a sealed source in a well without a surface casing to protect fresh water aquifers.

Applicants may use the format given in **Table 4** to provide the requested information.

Table 4. Sample Format for Providing Information About Requested Radioisotopes

Radioisotope	Chemical/Physical Form	Maximum Possession Limit	Proposed Use
Americium-241	Sealed neutron source (XYZ Inc., Model 10)	Not to exceed 5 curies per source	Oil, gas, and/or mineral logging.
Cesium-137	Sealed source (Okko Inc., Model 36)	Not to exceed 3 curies per source	Oil, gas, and/or mineral logging.
Hydrogen-3	Gas, titanium tritide neutron generator tube (Cols Inc., Model 3)	Not to exceed 3 curies per tube	Neutron activation logging in oil and gas wells in downhole accelerator
Iodine-131	Gas	100 millicuries total, not to exceed 20 millicuries per injection	Subsurface Tracer Operations
Iodine-131	Liquid	50 millicuries total, not to exceed 10 millicuries per injection	Subsurface Tracer Operations
Iridium-192	'Labeled' frac sand	200 millicuries total, not to exceed 15 millicuries per injection	Subsurface Tracer Operations
Cobalt-60	Metal wire	3 millicuries total, not to exceed 1 microcurie per individual unit	Pipe Joint Collar Markers, Subsidence Markers, Depth Determination
Silver-110m	Liquid	200 millicuries total, not to exceed 20 millicuries per injection	Field Flood Tracer Studies
Depleted Uranium	Sinker Bars	225 kilograms	Sinker Weights (Concentrated Mass)

If the material will be used in field flood studies where licensed material is intentionally released into the environment, an environmental assessment (EA) is required in accordance with appropriate United States Code regulations (**10 CFR 51.21**). NRC Supplement to Policy and Guidance Directive FC 84-20, *"Impact of Revision of 10 CFR Part 51 on Materials License Actions"*, Revision 1, provides criteria for determining when an EA is not needed. Applicants should note that authorization granted by VDH to use licensed material in tracer or field flood studies does not relieve them of their responsibilities to comply with any other applicable federal, state or local regulatory requirements.

Response from Applicant: No response required as long as the information was included in **Item 7.**

Item 8: Financial Assurance and Recordkeeping for Decommissioning

Rule: 12VAC5-481-450 C, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-571, 12VAC5-481-1161, 12VAC5-481-3350, 12VAC5-481-3360

Criteria: Financial assurance is not required by most well logging or tracer licensees; however, each licensee is obligated to maintain, in an identified location, decommissioning records related to facilities where licensed material is used, stored, or dispatched. Decommissioning records described above are not required at temporary jobsites. Pursuant to **12VAC5-481-450 C**, when terminating the license, licensees must transfer records important to decommissioning to either the new licensee before licensed activities are transferred or assigned according to **12VAC5-481-500** or the agency before the license is terminated.

Discussion: There are two parts to this rule: financial assurance that applies to some licensees and record keeping that applies to all licensees.

12VAC5-481-450 C, when applicable, require the applicant to provide financial assurance or a decommissioning funding plan. This is to provide reasonable assurance that, after the technical and environmental components of decommissioning are carried out, unrestricted use of the facilities is possible at the termination of licensed activities. The agency's primary objective is to ensure that decommissioning will be carried out with minimum impact on the health and safety of the public, occupationally exposed individuals, and the environment. These requirements specify that a licensee either set aside funds for decommissioning activities or provide a guarantee through a third party that funds will be available. Before a license is issued, applicants are required to submit financial assurance or decommissioning funding plan when requesting authorization to possess any sealed or unsealed radioactive material with half life greater than 120 days exceeding certain the limits. Criteria for this determination is described in **12VAC5-481-450 C**.

Most well logging, tracer, and field flood study licensees use only a few of radioisotopes with a half life greater than 120 days. The most frequently used radioisotopes requiring financial assurance in unsealed form are Hydrogen-3, Carbon-14, and Silver-110 metastable, and for sealed sources, Americium-241. **Table 5** provides a partial list of sealed and unsealed radioisotopes with a half life greater then 120 days with the corresponding limits. Radioisotopes with half lives greater then 120 days are listed in Column 1. Column 2 lists the corresponding possession limits of radioisotopes requiring financial assurance. Column 3 lists the corresponding possession limits of unsealed radioisotopes requiring the submittal of a decommissioning funding plan (DFP). These limits apply when only one of these radioisotopes is possessed. Applicants can use the data from **Table 5** or the method given in **Appendix I** to determine if financial assurance is required and the amount that is required when more than one of these radioisotopes is requested.

Table 5. Commonly Used Licensed Materials Requiring Financial Assurance/Decommissioning Funding Plan

Column 1: Radioisotope	Column 2: Limit for F/A (millicuries*)	Column 3: Limit for DFP (millicuries*)
Unsealed Materials		
H-3	1,000	100,000
C-14	100	10,000
Ag-110m	1	100
Sealed Materials		
Am-241	100,000	N/A

*1 millicurie = 37 MBq

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"* dated June 1990, contains approved wording for each mechanism authorized to guarantee or secure funds.

Record Keeping

The requirements for maintaining records important to decommissioning, including the type of information required, are stated in **12VAC5-481-450 C**. All licensees are required to maintain these records in an identified location until the site is released for unrestricted use. In the event that the licensed activities are transferred to another person or entity, these records shall be transferred to the new licensee before transferring 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 the agency.

12VAC5-481-450 C states the all of the records that must be maintained by a licensee important to decommissioning and that they must be transferred or assigned according to **12VAC5-481-450 C**, if a license is transferred or to the agency, before the license is terminated. Licensees must maintain permanent records on locations where licensed materials are used or stored while the license is in force. These permanent records are important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). Acceptable permanent records include sketches, written descriptions of specific locations where radioactive material is used or stored, and records of any leaking sealed sources, tracer material spills, contaminated waste storage areas, or other unusual occurrences involving the spread of contamination in or around the licensee's facilities or field stations. Permanent decommissioning records described above are not required for temporary job site locations.

Response from Applicants:

Item 8 Financial Assurance And Recordkeeping For Decommissioning (Check both boxes)
☐ We shall maintain drawings and records important to decommissioning and will transfer these records to a new licensee before licensed activities are transferred in accordance with **12VAC5-481-500 B** or assign the records to the agency before the license is terminated.
AND
☐ If financial assurance is required, submit evidence per **12VAC5-481-450 C**.

References: NRC RG 3.66 and Policy and Guidance Directive FC 90-2 (Rev. 1), "*Standard Review Plan for Evaluating Compliance with Decommissioning Requirements*", dated April 30, 1991.

Item 9: Facilities and Equipment

Rule: 12VAC5-481-450, 12VAC5-481-630, 12VAC5-481-720, 12VAC5-481-840, 12VAC5-481-850, 12VAC5-481-860, 12VAC5-481-880, 12VAC5-481-930, 12VAC5-481-3170, 12VAC5-481-3180, 12VAC5-481-3200, 12VAC5-481-3250, 12VAC5-481-3260, 12VAC5-481-3300, 12VAC5-481-3310, 12VAC5-481-3330, 12VAC5-481-3350, 12VAC5-481-3360

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

Discussion: Applicants must demonstrate that proposed facilities and equipment provide adequate storage capabilities, ensure that appropriate shielding is available to protect the health and safety of the public and employees, keep exposures to radiation and radioactive materials ALARA, and minimize the possibility of contamination from the uses, types, and quantities of radioactive materials requested.

Licensed materials located in an unrestricted area and not in storage must be under the constant surveillance and immediate control of the licensee. Areas where material is used or stored, including below ground bunker storage areas, should (1) be accessible only by authorized persons; and (2) secured or locked when an authorized person is not physically present. Use or storage areas cannot be considered restricted areas for purposes of radiation safety if accessible by unauthorized persons.

Applicants may delay completing facilities and acquiring equipment until after the application review is completed. Delaying the acquisition will allow for changes, if any, needed as a result of the application review. This delay will also ensure the adequacy of proposed facilities and equipment before the applicant makes a significant financial commitment. In all cases, the applicant cannot possess or use licensed material until after the facilities are approved, equipment is procured, and the license is issued.

Provide the following, as applicable:

- A drawing or sketch to an indicated scale or including dimensions of each proposed facility identifying areas where radioactive materials, including radioactive wastes, will be used or stored as well as adjacent buildings, boundary lines, security fences, and lockable storage areas. Illustrate area(s) where explosive, flammable, or other hazardous materials will be stored and the relationship and distance between restricted areas and unrestricted areas. Specify shielding materials (concrete, lead, etc) and means for securing radioactive materials from unauthorized removal.
- A drawing or sketch of proposed tracer material storage facilities including rooms, buildings, below ground bunker storage areas, or containers used for storage of both tracer and tracer waste materials; specifying the types and amount of shielding materials (concrete, lead, etc.) and means for securing tracer materials from unauthorized removal.
- Describe protective clothing (such as rubber gloves, coveralls, respirators, and face shields), auxiliary shielding, absorbent materials, injection equipment, secondary containers for waste water storage for decontamination purposes, plastic bags for storing contaminated items, etc., that will be available at well sites when using tracer materials.
- Describe proposed laundry facilities used for contaminated protective clothing, and specify how the contaminated waste water from the laundry machines or sinks is disposed. Operating and emergency procedures should address decontamination of the laundry area and equipment.
- Describe proposed decontamination facilities for trucks, tracer injection tools, or other equipment contaminated by tracer materials and specify how the contaminated waster water will be disposed. Operating and emergency procedures should address decontamination of these types of equipment and facilities.
- Describe equipment for 'repackaging' gaseous, volatile, or finely divided tracer material. Most tracer users do not repackage materials and acquire their injections in pre-calibrated amounts or 'ready to use' forms. However, should an applicant request the ability to repackage tracer, volatile, or finely divided materials, consider the following equipment when repackaging tracer materials: sinks, trays with absorbent material, glove boxes, fume hoods with charcoal filtration, filtered exhaust, special handling equipment including special tools, rubber gloves, etc.

12VAC5-481-930 authorizes the disposal of readily soluble radioactive materials via the sanitary sewage. Sanitary sewage does not include sewage treatment facilities, septic tanks, and leach fields owned or operated by a licensee.

Response from Applicant:

Item 9 Facilities And Equipment (Check box and attach requested information)
☐ We will submit the required information as listed in the section titled "Facilities and Equipment" of VAREG 'Guidance for Well Logging,, Tracer, and Field Flood Study'.

Item 9.1 Minimization of Contamination

Rule: 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-630, 12VAC5-481-730, 12VAC5-481-740, 12VAC5-481-750, 12VAC5-481-1150, 12VAC5-481-1161, 12VAC5-481-3200 A, 12VAC5-481-3210, 12VAC5-481-3280, 12VAC5-481-3340, 12VAC5-481-3370

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

Discussion: When designing facilities and developing procedures for their safe use, applicants should plan 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 while performing operations
- Minimization of distance to areas, to the extent practicable, where licensed materials are used and stored
- Maximization of survey frequency, within reason, to enhance detection of contamination
- Segregation of radioactive material in waste storage areas
- Segregation of sealed sources and tracer materials to prevent cross-contamination
- Separation of radioactive material from explosives
- Separation of potentially contaminated areas from clean areas by barriers or other controls.

Sealed sources found to be leaking in excess of 185 bequerels (0.005 microcuries) of removal contamination must be immediately withdrawn from use and placed in a safe storage location until disposed of according to VDH requirements. Special authorization must be granted by VDH to applicants to decontaminate a facility contaminated by a leaking sealed source. Approval granted in a license by VDH, NRC, or another Agreement State to provide these specialized services minimizes the spread of contamination and reduces radioactive waste associated with decontamination efforts.

Response from Applicant: None for this item; it has been included in other responses.

Item 10: Radiation Safety Program

Rule: 12VAC5-481-450, 12VAC5-481-630, 12VAC5-481-990, 12VAC5-481-3151, 12VAC5-481-3260, 12VAC5-481-3280

Criteria: A radiation safety program must be established and submitted to the agency as part of the application. The program must be commensurate with the scope and extent of activities for the use of licensed materials in well logging, tracer, and field flood study operations. Each applicant must develop, document, and implement a radiation protection program containing the following elements:

- Development and implementation of an ALARA program
- Description of equipment and facilities adequate to protect personnel, public, and the environment
- Confirmation that licensed activities are conducted only by individuals qualified by training and experience
- Development and maintenance of written operating and emergency procedures
- Implementation of an audit program to inspect the job performance of well logging supervisors and assistants
- Description of organization structure and individuals responsible for ensuring day-to-day oversight of the radiation safety program
- Establishment and management of a radiation safety and decommissioning records system.

Discussion: Individual components of a radiation safety program are addressed in the topics found in this VAREG. Some topics will not require the applicant to submit information as part of an application, but simply provide the applicant with guidance to comply with a specific VDH requirement. Applicants who plan to conduct well logging operations using sealed sources, tracer materials or tracer materials in field flood study operations are required to submit, for VDH approval, their operating and emergency procedures or, optionally, to provide either an outline or summary of each procedure that includes the important radiation safety aspects of each individual procedure.

Radiation safety programs including tracer materials must assure that they address these additional concerns:
methods or procedures for preventing the release of contaminated material, equipment or vehicles to unrestricted use from tracer or field flood study operations, radiation safety procedures and the well logging supervisors' responsibilities unique to tracer and field flood study operations, and tracer and field flood study equipment, techniques, and corresponding radiation safety procedures associated with use of tracer materials.

Appendix F includes a description of procedures for using tracer materials in field flood study operations.

Response from Applicant:

Item 10. Radiation Safety Program (Check box)
☐ We have included our radiation safety program for agency review.

Item 10.1 Well Owner/Operator Agreement

Rule: 12VAC5-481-480 B, 12VAC5-481-3160, 12VAC5-481-3340, 12VAC5-481-3370

Criteria: Well logging conducted with a sealed source shall only be performed if a written agreement with the employing well owner or operator is executed prior to commencement of the operation.

Discussion: Well logging operations conducted using a sealed source are performed only after a written agreement is executed with the employing well owner or operator. Written agreements

must identify a responsible party for ensuring that the following steps will be taken if a source becomes lodged in a hole:

- A reasonable effort will be made to recover the source
- A person will not attempt to recover a lodged sealed source in a manner that, in the licensee's opinion, could result in its rupture
- During efforts to recover a sealed source, a licensee must continuously monitor the circulating fluids in the well bore, as required in **12VAC5-481-3340 G.**
- Contaminated equipment, personnel, or environment must be decontaminated prior to release
- If a sealed source is classified by the licensee as irretrievable after reasonable efforts at recovery have been expended, the following must be implemented within 30 days, as shown in **Figure 2**:
  - — Source must be immobilized and sealed in place with a cement plug and there must be a means to prevent inadvertent intrusion, unless the source is not accessible to any subsequent drilling operations
  - — Install a permanent identification plaque at the surface of the well, unless mounting of a plaque is not practical. **Figure 3** provides a diagram of a permanent identification plaque, describing the information that should be included on the plaque.
  - — Notify the agency by telephone of the circumstances that resulted in the inability to retrieve the source and obtain approval to implement abandonment procedures.
- Send a copy of the abandonment report within 30 days of the abandonment of the sealed source, to the agency and Virginia Department of Mines, Minerals, and Energy; Division of Gas and Oil. The abandonment report must contain all the information outlined in **12VAC5-481-3370 C 3.** Refer to **Appendix Q** for additional guidance.

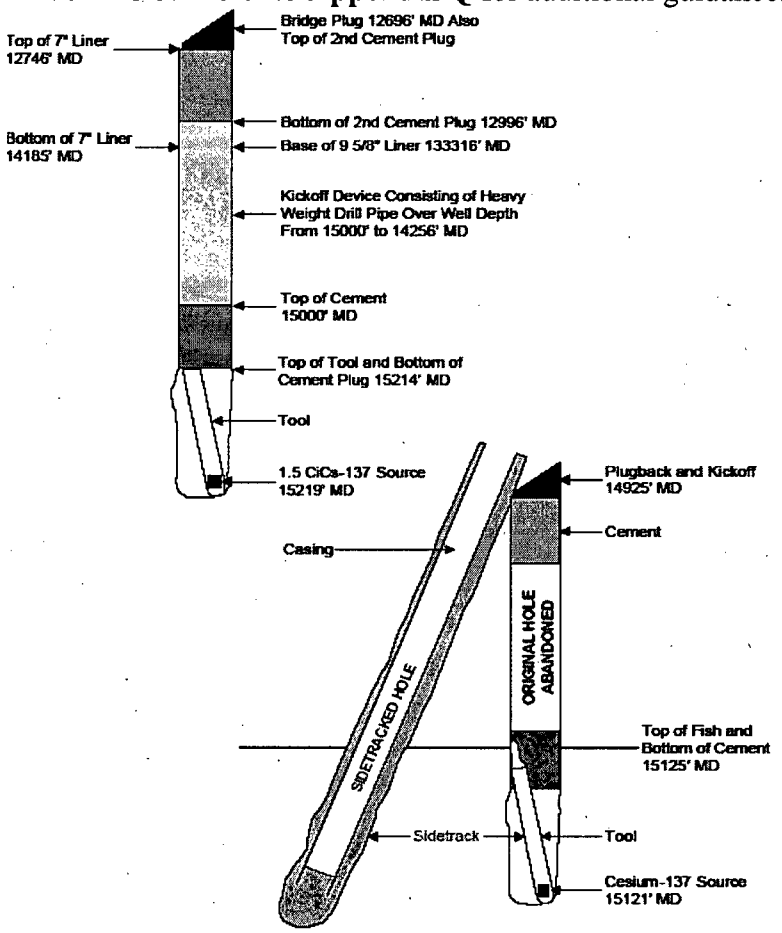


Figure 2. Features of a Typical Source Abandonment.

The agency is aware that in some circumstances, such as high well pressures that could lead to fires or explosions, the delay required to obtain approval to abandon the well may introduce an immediate threat. **Under such exigent circumstances, immediate abandonment, without prior approval, is authorized if a delay could cause an immediate threat to public health and safety.** Notification would be made as soon as possible after the abandonment. See **12VAC5-481-3370 C.**

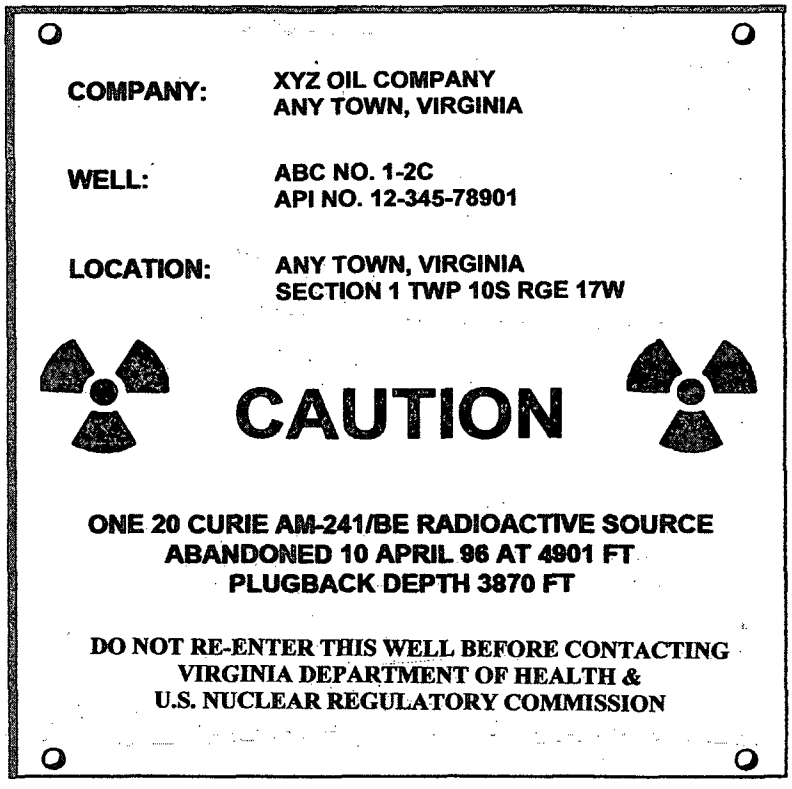


Figure 3. Permanent Identification Plaque.

Note: A written agreement is not required if the licensee and well owner or operator are part of the same corporate structure or otherwise similarly affiliated. However, all other requirements must still be met. If the requirement for a written agreement does not apply to you, then you should include a statement in your application that you will only log holes where the well owner or operator is part of your corporate structure or otherwise similarly affiliated, and you should describe the corporate affiliation.

Response from Applicant:

Item 10.1 Well Owner/Operator Agreement

☐ We will obtain a written agreement prior to commencement of operating any well logging operation with a sealed source as specified in **12VAC5-481-3160.**

Item 10.2 Radiation Safety Program Audit

Rule: 12VAC5-481-630, 12VAC5-481-990, 12VAC5-481-3151

Criteria: Licensees must review the content and implementation of their radiation protection programs 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 (**12VAC5-481-630**), records of audits and other reviews of program content and implementation are maintained for 3 years.

Discussion: Licensees are encouraged to implement as part of the radiation safety program a self-assessment and corrective action tracking program. Assessments necessary to ensure safe operations should result in a continuous process to self-identify violations, implement immediate corrective action when required, and track to completion and close-out of self-identified violations. The agency's enforcement policy is designed to encourage and to give credit to licensees for self-identifying violations and for taking immediate corrective actions. This policy allows licensees with a good regulatory performance, as shown by a licensee's inspection history, to be inspected less frequently than licensees where the agency has identified significant violation(s) during an inspection. Although the annual ALARA audit required by **12VAC5-481-630** is an important cornerstone of the radiation safety program, the agency encourages applicants/licensees to develop and implement an ongoing audit program and corresponding corrective action tracking program.

Appendix G contains a suggested annual audit program that is specific to well logging and tracer operations and is acceptable to the agency. All areas indicated may not be applicable to every licensee and may not need to be addressed during each audit.

Response from Applicant:

Item 10.2 Radiation Safety Audit Program
The applicant is not required to, and should not, submit its audit program to the agency for review during the licensing phase. This matter will be examined during an inspection.

Item 10.3 Termination of Activities

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

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

- Notify the agency, in writing, within 60 days of:
  — the expiration of its license
  — a decision to permanently cease licensed activities at the entire site (regardless of contamination levels)
  — a decision to permanently cease licensed activities in any separate building or outdoor area, if they contain residual radioactivity making them unsuitable for release according to VDH requirements

— no principal activities having been conducted at the entire site under the license for a period of 24 months
— no principal activities having not been conducted for a period of 24 months in any separate building or outdoor area, if they contain residual radioactivity making them unsuitable for release according to VDH requirements.

- Submit decommissioning plan, if required by **12VAC5-481-510**.
- Conduct decommissioning, as required by **12VAC5-481-510** and **12VAC5-481-1161**.
- Submit, to the agency, a completed VDH form, 'Certificate of Disposition of Materials' (**Appendix B**) and a demonstration 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 the agency. If licensed activities are transferred or assigned in accordance with **12VAC5-481-500**, transfer records important to decommissioning to the new licensee.

Discussion: As discussed above, before a licensee can decide whether it must notify the agency, the licensee must determine whether residual radioactivity is present and, if so, whether the levels make the building or outdoor area unsuitable for release according to VDH requirements. A licensee's determination that a facility is not contaminated is subject to verification by VDH inspection.

The permanent cessation of principal activities in an individual room or laboratory may require the licensee to notify the agency if no other licensed activities are being performed in the building. NRC Draft Regulatory Guide DG-4006, *"Demonstrating Radiological Criteria For License Termination"*, issued July 8, 1998 and 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 the Handbook contains a comprehensive list of NRC's decommissioning regulations and guidance. 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. An acceptable screening computer code for calculating screening values to demonstrate compliance with the unrestricted dose limits is D and D, Version 1; this was issued on August 20, 1998. Supplemental information on the implementation of the final rule on radiological criteria for license termination was published in the Federal Register (Volume 63, Number 222, Page 64132-64134) on November 18, 1998. This includes the acceptable license termination screening values of common radionuclides for building surface contamination (see **Table 6**).

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

Radionuclide	Symbol	Acceptable Screening Levels*
Hydrogren-3 (Tritium)	H-3	1.2 x 108
Carbon-14	C-14	3.7 x 106
Sodium-22	Na-22	9.5 x 103
Sulfur-35	S-35	1.3 x 107
Iron-55	Fe-55	4.5 x 106
Cobalt-60	Co-60	7.1 x 103
Nickel-63	Ni-63	1.8 x 106
Strontium-90	Sr-90	8.7 x 106
Cesium-137	Cs-137	2.8 x 104
Iridium-192	Ir-192	7.4 x 104

* 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 then 0.1, users may assure, 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 may have site-specific data on the fraction of removable contamination (e. g., within 10% to 100% range) may calculate site-specific screening levels using D and D Version 1, based on site-specific re-suspension factor. For Unrestricted Release (dpm/100 cm^2). 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 released dose limit in **12VAC5-481-1161 B**. For radionuclides in a mixture, the 'sum of fractions' rule applies; refer to NRC Draft Guidance DG-4006 for further information on application of the values in this table.

Response from Applicant:

Item 10.3 Termination of Activities (Check box)

☐ We will notify VDH, in writing, within 60 days of the decision to permanently cease radioactive material use. **(12VAC5-481-510)**

Reference: VDH form, 'Certificate of Disposition of Materials', is included in **Appendix B**.

Item 10.4 Radiation Monitoring Instruments

Rule: 12VAC5-481-450 A, 12VAC5-481-750, 12VAC5-481-900, 12VAC5-481-1000, 12VAC5-481-1161, 12VAC5-481-3070, 12VAC5-481-3200.

Criteria: Licensees must possess radiation monitoring instruments that are necessary to protect health and minimize danger to life or property. Instruments used for quantitative radiation measurements must be calibrated for the radiation that it is used to measure at least every 6 months. For the purposes of this document, survey instruments are defined as any device used to measure the radiological conditions at a licensed facility, field station, or temporary job site.

Discussion: For well logging and tracer operations, instruments must be capable of measuring 0.001 millisievert (0.1 mrem) per hour through at least 0.5 millisievert (50 mrem) per hour. Licensees shall possess operable and calibrated radiation detection/measurement instruments to perform the following: surveys of package(s), vehicle(s), tracer material equipment, vehicles, personnel, and sites, unrestricted areas, and sealed sources.

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 that applicants intend to purchase prior to starting licensed activities. The description should include type of instrument and probe, and the instrument's intended purpose.
The agency 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 N** provides information about instrument specifications and model calibration procedures.

Response from Applicant:

Item 10.4 Radiation Monitoring Instruments (Check all boxes that apply)

☐ We will possess and use radiation survey meter(s) that meets the Criteria in the section titled 'Radiation Monitoring Instruments' in VAREG, 'Guidance for Well Logging, Tracer, and Field Flood Studies'. We reserve the right to upgrade our survey instruments as necessary.

AND EITHER

☐ If calibration is performed by a person or firm outside the applicant's organization, the calibration will be performed by a VDH, NRC, or another Agreement State licensee specifically authorized to perform instrument calibration.

OR

☐ We will follow the survey meter calibration procedures in accordance with Appendix N in VAREG 'Guidance for Well Logging, Tracer, and Field Flood Study'.

OR

☐ We will submit alternate procedures. (Procedures are attached)

Note: Identify the qualifications of the individuals who will perform the calibrations if performed by the applicant.

Note: Alternative responses will be reviewed using the criteria listed above.

Item 10.5 Material Receipt and Accountability

Rule: 12VAC5-481-100, 12VAC5-481-450 C, 12VAC5-481-500, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-840, 12VAC5-481-900, 12VAC5-481-980, 12VAC5-481-1060, 12VAC5-481-1080, 12VAC5-481-3091, 12VAC5-481-3100, 12VAC5-481-3220, 12VAC5-481-3261

Criteria: Licensees with licensed material must do the following: maintain records of receipt, transfer, and disposal of licensed materials, conduct physical inventories of licensed materials at least every 3 months to account for all sealed sources, tracer materials, and depleted uranium, and maintain inventory records 3 years from the date of the inventory.

Discussion: Licensed materials must be tracked from the time of receipt to disposal in order to ensure accountability, identify when licensed material is lost, stolen, or misplaced, and to ensure that possession limits listed on the license are not exceeded. Physical inventories include locating, verifying the physical presence, and/or accounting for materials by the use of material receipt and transfer records.

Inventory records must contain the following types of information: quantity and kind of licensed material including sealed sources, tracer material on hand (including waste), and depleted uranium in sinker bars; location of each sealed source; date the inventory occurred; and name of individual performing the inventory.

Note: Physical inventory records may be combined with leak test records.

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

Response from Applicant:

Item 10.5 Material Receipt And Accountability (Check box)

☐ Semi-annual physical inventories will be conducted of all licensed material, including byproduct, tracer materials, and depleted uranium and the information contained in the discussion section titled 'Material Receipt and Accountability' in VAREG 'Guidance for Well Logging, Tracer, and Field Flood Studies' will be documented.

Item 10.6 Leak Tests

Rule: 12VAC5-481-740, 12VAC5-481-750, 12VAC5-481-1010, 12VAC5-481-1150, 12VAC5-481-3151, 12VAC5-481-3210

Criteria: VDH requires testing of sealed sources containing greater than 3.7 MBq (100 microcuries) of beta/gamma or 0.37 MBq (10 microcuries) of alpha radioactive material in order to determine whether there is any radioactive leakage from sealed sources. Requirements for leak tests are based on the type of radiation (beta/gamma/alpha) escaping from the inner capsule. Records of test results must be maintained per **12VAC5-481-3210**.

Discussion: VDH licenses will require the performance of leak tests on sealed sources authorized for well logging at intervals approved by the agency and as specified in the SSD Registration Sheet. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 becquerels (0.005 microcuries) of radioactivity.

Manufacturers, consultants, and other organizations may be authorized by VDH, NRC, or another Agreement State either to perform the entire leak test sequence for other licensees or to provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample according to the manufacturer's and the kit supplier's instructions and return it to the kit supplier for evaluation and reporting results. Licensees may also be authorized to conduct the entire leak test sequence themselves.

Response from Applicant:

Item 10.6 Leak Tests (Check one box)

☐ Leak tests will be performed by an organization authorized by VDH, the NRC or another Agreement State to provide leak testing services toother licensees; or by the licensee 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 tests (Specify whether VDH, NRC, or another Agreement State):

Organization Name _____ License Number _____

Issuing Entity _____

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 R of VAREG 'Guidance for Well Logging, Tracer, and Field Flood Study'.

OR

☐ We will submit alternative procedures. (Procedures are attached)

Note: Requests for authorization to perform leak testing and sample analysis will be reviewed on a case-by-case basis and, if approved, VDH staff will authorize via a license condition. Alternative procedures will be evaluated against **Appendix R** criteria.

References: NRC Draft Regulatory Guide FC 412-4, *"Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services"*, is available from NRC upon request.

Item 10.7 Occupational Dosimetry

Rule: 12VAC5-481-640, 12VAC5-481-650, 12VAC5-481-700, 12VAC5-481-710, 12VAC5-481-740, 12VAC5-481-750, 12VAC5-481-760, 12VAC5-481-3290, 12VAC5-481-3690

Criteria: According to **12VAC5-481-3290**, logging supervisors and logging assistants must wear either film badges or thermoluminescent dosimeters (TLDs) during the handling or use of licensed radioactive material. This requirement applies to personnel using dosimeters for whole body measurements. Although not included in **12VAC5-481-3290**, VDH and some other Agreement States have authorized Optically Stimulated Luminescence (OSL) dosimetry devices approved by the National Voluntary Laboratory Accreditation Program (NVLAP). NRC is currently in the process of amending its regulations to authorize the use of OSL dosimetry devices. Licensees must provide to employees, either a film, OSL, or TLD that is processed by an accredited entity under the NVLAP operated by the National Institute of Standards and Technology (NIST).

Appendix O provides guidance for determining if individuals other than the RSO, logging supervisors, or logging assistants require dosimetry.

Bioassay services required in a license must be provided to individuals using tracer materials in subsurface studies if required by the license.

Table 7. Occupational Dose Limits for Adults.

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

Discussion: The licensee may not permit any individual to act as a logging supervisor or logging assistant unless, at all times during the handling of licensed radioactive material, each individual wears on the trunk of the body a NVLAP-approved film badge, TLD, or OSL/personnel dosimeter (if specifically approved by VDH) that is sensitive to the type of radiation(s) to which the individual is exposed. If neutron sources are to be used, a commitment to provide neutron sensitive dosimetry devices is required. Film badges must be replaced at intervals not to exceed 1 month and TLDs or OSL must be replaced at intervals not to exceed 3 months.
For purposes of internal dosimetry, bioassays are required when individuals work with volatile radioactive material in the quantities, chemical and physical forms, and activities that make it likely that the radionuclide will be ingested, inhaled, or absorbed resulting in an intake in excess of 10% of the applicable annual limit on intakes (ALIs) in **12VAC5-481-3690**. One ALI results in a committed effective dose equivalent (CEDE) of 5 rems or a committed dose equivalent (CDE) of 50 rems.

When using individually packaged 'ready to use' quantities of Iodine-131 tracer materials in well logging operations, bioassays are required for individuals using more than 50 millicuries at any one time, or using a total of 50 millicuries within any 5-day period. Guidance on bioassay programs for Iodine-131, including the levels and types of handling for which bioassays are indicated, is provided in the NRC Regulatory Guide 8.20, *"Applications of Bioassay for iodine-125 and iodine-131"*. Copies may be obtained from NRC's Regional Offices or online at http://www.nrc.gov. Bioassay services are available and provided by local hospitals, universities, or other vendors specifically approved to provide such services.

Bioassay programs should include what the applicant considers an acceptable interval or schedule for conducting bioassays, identify action levels or guidelines, and describe specific actions to be taken when action levels are exceeded. Because of the complex nature of bioassay and corresponding data analysis, it is acceptable for applicants to make reference to the procedures in VDH or NRC guidance documents.

Response from Applicant:

Item 10.7 Occupational Dosimetry (Check all boxes that apply)

☐ We will provide required dosimetry that will be processed and evaluated by a NVLAP-approved processor that is exchanged monthly or quarterly, as appropriate, and worn by well logging personnel.

AND/OR

☐ We will provide a bioassay program when using unsealed tracer materials.

OR

☐ We will provide a commitment that no individual will use more than 50 millicuries of Iodine-131 at any one time or in any 5-day period at field stations or temporary job sites.

Note: If intend to use an excess of amounts described or request permission to repackage or process Iodine-131 tracer materials at field stations, it is necessary to describe in detail the bioassay program

OR

☐ We will contract an vendor for bioassay services who is licensed or otherwise authorized by VDH, NRC, or another Agreement State to provide required bioassay services.

To obtain a copy of the NIST Publication 810, *"National Voluntary Laboratory Accreditation Program, 1997 Directory"*, contact the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9225. (For information on the program, call NIST at 301-975-3679.) Also, NVLAP maintains a directory of accredited laboratories on the Internet (updated quarterly); the URL for NVLAP's home page on the Internet is http://ts.nist.gov/nvlap.

Item 10.8 Public Dose

Rule: 12VAC5-481-630, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-840, 12VAC5-481-1050, 12VAC5-481-3070, 12VAC5-481-3190, 12VAC5-481-3250, 12VAC5-481-3280, 12VAC5-481-3300

Criteria: Licensees must do the following: 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; control and maintain constant surveillance of licensed material when in use and not in storage; and secure stored licensed material from access, removal, or use by unauthorized personnel.

Discussion: Members of the public include persons who work in or may occupy locations where licensed material is used or stored. Employees whose assigned duties do not include the use of licensed material and work in the vicinity where it is used or stored are also included as members of the public. Public dose is controlled, in part, by ensuring that licensed material is secured (e.g., located in a locked area) to prevent unauthorized access or use. Well logging sealed sources and tracer materials are usually restricted by controlling access to the keys needed to gain access to storage locations, including downhole storage bunkers.

Public dose is also affected by the choice of storage and use locations at the field stations and at temporary job sites. Licensed material must be located so that the resulting 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. Applicants should use the concepts of controlling time, distance, and shielding when choosing storage and use locations. Decreasing the time that an individual is exposed, increasing the distance from the radioactive material, and adding shielding that is appropriate for the specific type of radiation (e.g., brick, concrete, lead, hydrogenous materials, etc.) will reduce the radiation exposure.

Information provided by the manufacturer or vendor on anticipated radiation levels of sealed sources and tracer materials, both inside their respective transport containers and outside the transport container at given distances, is the type of information needed to make public dose calculations. Licensees may assess radiation levels located in adjacent areas to radioactive material either by making calculations or by using a combination of direct measurements and calculations. After obtaining anticipated radiation levels or by making direct radiation measurements using an appropriate survey instrument, an applicant can use the 'inverse square' law to evaluate the effect on the public and use this information to determine operating and emergency procedures for using radioactive materials. See **Appendix P** for an example demonstrating that individual members of the public will not receive doses exceeding the allowable public limits.

If, after making an initial public dose evaluation, a licensee changes the conditions used for the evaluation (e.g., relocates radioactive material within a designated storage area, increases the amount of radioactive materials are in storage, changes the frequency radioactive material is in use, or changes 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, if required.

Response from Applicant:

Item 10.8 Public Dose
No response is required, in this license application, however the licensee's evaluation of public dose will be examined during an inspection.

See **Appendix P** for examples of methods to demonstrate compliance.

Item 10.9 Maintenance

Rule: 12VAC5-481-1080, 12VAC5-481-3180, 12VAC5-481-3190, 12VAC5-481-3250, 12VAC5-481-3260, 12VAC5-481-3261, 12VAC5-481-3280, 12VAC5-481-3300

Criteria: The licensee shall have written procedures for visually inspecting and for maintaining source holders, logging tools, and source handling tools in an operable condition, including labeling. If equipment problems are found, the equipment must be withdrawn from service until repaired. Records of this inspection program are required.

Discussion: Each licensee shall visually check source holders, logging tools, and source handling tools for defects prior to each use to ensure that the equipment is in good working order and that required labeling is present. If defects are found, the equipment must be removed from service until repaired and a record made of the defect and the repairs made prior to returning the equipment for use. At intervals not to exceed 6 months, licensees shall conduct a visual inspection to ensure that no physical damage to equipment is visible and the required labeling is present. Licensees must establish a program for the routine maintenance of source holders, logging tools, inspection tools, source handling tools, storage containers, transport container, injection tools, and uranium sinker bars. If defects are found during the visible inspection or during the routine maintenance, the equipment must be removed from service until repaired and a record made of the defect and any repairs made prior to returning the equipment for use.

Non-routine and special maintenance (e.g., change of O rings on sealed sources or removal of a stuck sealed source) in a manner that could potentially damage or rupture the source, can only be performed by those licensees that have specifically received authorization from the VDH, NRC or another Agreement State. If defects are found as a result of the inspection and maintenance programs, the equipment must be removed from service until repairs are made, and a record of the defect must be retained for 3 years after the defect is found.

Response from Applicant: No response required; included in other items.

Item 10.9.1 Daily Maintenance

Rule: 12VAC5-481-880, 12VAC5-481-3180, 12VAC5-481-3190, 12VAC5-481-3250, 12VAC5-481-3260, 12VAC5-481-3280

Criteria: The licensee must have written procedures for visually inspecting and maintaining source holders, logging tools, and source handling tools for defects prior to use. This visual inspection is necessary to ensure that the equipment remains in good working condition and is labeled as required.

Discussion: 12VAC5-481-3260 A requires that logging tools, source holders, and source handling tools be checked visually for defects prior to use to ensure that the equipment is in good working condition and is labeled as required. Labeling requirements are specified in **12VAC5-481-3250**. Instructions in the operating procedures provided to personnel must clearly reflect the regulatory requirement—visual inspections are performed prior to use. Record after the inspection: the date, inspector, equipment involved, any defects found, or repairs made. Equipment that fails the inspection and cannot be repaired must be removed from service and returned only after it is successfully repaired.

The licensee must develop, implement, and maintain procedures for visually inspecting and maintaining source holders, logging tools, and source handling tools.

Response from Applicant:

Item 10.9.1 Daily Maintenance (Check both boxes)
☐ We have included procedures for conducting daily visual inspection.
OR
☐ Visual daily inspection will be conducted and records maintained in accordance with the criteria listed in 'Daily Maintenance' of the VAREG'Guidance for Well Logging, Tracer, and Field Flood Study' to ensure that well logging equipment is in good working condition and is labeledas required.

Item 10.9.2 Semi-Annual Visual Inspection and Routine Maintenance

Rule: 10 CFR 21.21, 12VAC5-481-880, 12VAC5-481-3180, 12VAC5-481-3190, 12VAC5-481-3250, 12VAC5-481-3260

Criteria: Licensees must have written procedures for semiannual visual and routine maintenance of source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars to ensure that the labeling required by **12VAC5-481, 'Virginia Radiation Protection Regulations'** is legible and that no physical damage to the equipment is visible. Requirements in **10 CFR 21.21** specify, in part, that licensees adopt appropriate procedures to notify the NRC of any equipment that is defective or could result in a substantial safety hazard, and additionally, that management be informed as soon as practicable, within 5 working days, after the completion of the evaluation.

Discussion: Logging supervisors or assistants are expected to conduct visual inspections and provide routine maintenance activities on source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars to ensure that the labeling required by **12VAC5-481-880** and **12VAC5-481-3250** for sealed sources and for uranium sinker bars is legible, and that no physical damage is visible. If defects are found, the equipment must be removed from service, and a record must be made, listing: the defects, inspection and maintenance operations performed, and the actions taken to correct the defects. As noted in **12VAC5-481-3280 9**, instructions for conducting these activities must be included as part of the operating and emergency procedures. Instructions should be tailored to your specific program and to the equipment possessed and used.

Reporting defects, in accordance with **10 CFR 21.21**, is a management responsibility. The specific mechanism or procedures for reporting to the agency need not be covered in instructions to personnel.

Response from Applicant:

Item 10.9.2 Semi-Annual Visual Inspection and Routine Maintenance (Check both boxes)
☐ We have included procedures for semi annual visual inspection and routine maintenance of source holders, logging tools, injection tools,source handling tools, storage containers, transport containers, and uranium sinker bars to ensure that the labeling required by**12VAC5-481-3250** is legible and that no physical damage is visible.
OR
☐ Semi-annual inspections and routine maintenance will be conducted and records maintained for source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars in accordance with the criteria in 'Semi-Annual Visual Inspection and Routine Maintenance' of VAREG 'Guidance for Well Logging, Tracer, Field Flood Study' to ensure that well logging equipment is in good working condition with no physical damage evident and that required labeling is present.

Item 10.9.3 Maintenance Requiring Special Authorization

Rule: 12VAC5-481-500, 12VAC5-481-3260, 12VAC5-481-3280

Criteria: Certain maintenance procedures on sealed sources or holders that contain sealed sources are prohibited, unless a written procedure has been approved and the licensee is specifically authorized by the VDH, NRC or another Agreement State to perform these operations.

Discussion: Activities that are prohibited, unless a written procedure has been reviewed and approved by VDH, NRC, or another Agreement State, include:

- Removing a sealed source from a source holder or logging tool
- Preventive maintenance activities on sealed sources or holders that may be necessary when using certain types of logging tools, including removing and replacing O-rings
- Removing a sealed source that is stuck in a source holder or logging tool, e.g., any situation where tools are required to remove the stuck source.

Response from Applicant:

Item 10.9.3 Maintenance Requiring Special Authorization (Check both boxes)
☐ Prohibited activities described in 'Maintenance Requiring Special Authorization' of VAREG 'Guidance for Well Logging, Tracer, Field Flood Study' will not be conducted unless approved by VDH.
OR
☐ Submit detailed procedures of each different tasks (including source removal procedures) for any prohibited activities, including radiation safety precautions that individuals will be expected to follow when performing these tasks and the minimum qualifications of these individuals.

Note: Equipment manufacturers can provide information concerning maintenance and source removal procedures. In some cases, certain maintenance operations should only be performed by the manufacturer or individuals who are licensed by VDH, NRC, or another Agreement State to provide these services.

Item 10.10 Operating and Emergency Procedures

Rule: 12VAC5-481-450 A, 12VAC5-481-840, 12VAC5-481-900, 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-2980, 12VAC5-481-3091, 12VAC5-481-3151, 12VAC5-481-3200, 12VAC5-481-3260, 12VAC5-481-3280, 12VAC5-481-3290, 12VAC5-481-3340, 12VAC5-481-3370

Criteria: The licensee must develop, implement, and maintain operating and emergency procedures or submit a summary of the procedures that addresses the important radiation safety aspects of each procedure to the agency as part of the application package. Additionally, if well logging and tracer personnel perform specific operations such as leak-testing, semi-annual inspection and maintenance of equipment, and removal and replacement of a sealed source O-ring, appropriate procedures and instructions for these operations should be included in the applicant's operating and emergency procedures.

Each licensee must develop, implement, and maintain operating and emergency procedures. Operating and emergency procedures' elements must include the items outlined in **12VAC5-481-3280**. The following is provided as a checklist of important items:

- Instructions for handling and using licensed materials, including sealed sources in wells, without surface casing for protecting fresh water aquifers
- Instructions for maintaining security during storage and transportation
- Instructions to keep licensed material under control and under immediate surveillance during use
- Steps to take to keep radiation exposures ALARA
- Steps to maintain accountability during use
- Steps to control access to work sites
- Steps to take and whom to contact when an emergency occurs
- Instructions for using remote handling tools when handling sealed sources, except low-activity calibration sources and radioactive tracer materials
- Methods and occasions for conducting radiation surveys, including surveys for detecting contamination, as required by **12VAC5-481-3340**.
- Procedures to minimize personnel exposure during routine use and in the event of an incident, including exposures from inhalation and ingestion of licensed tracer materials
- Methods and occasions for locking and securing stored licensed materials
- Personnel monitoring, including bioassays, and the use of personnel monitoring equipment
- Transportation of licensed materials to field stations or temporary job sites, packaging of licensed materials for transport in vehicles, placarding of vehicles when needed, and physically securing licensed materials in transport vehicles during transportation to prevent accidental loss, tampering, or unauthorized removal
- Procedures for picking up, receiving, and opening packages containing licensed materials, in accordance with **12VAC5-481-900**.
- Instructions for the use of tracer materials, including how to decontaminate the environment, equipment, and personnel
- Instructions for maintaining records in accordance with the regulations and the license conditions
- Steps for the use, inspection, and maintenance of sealed sources, source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars, as required by **12VAC5-481-3260**.
- Actions to be taken if a sealed source is lodged in a well
- Procedures and actions to be taken if a sealed source is ruptured, including actions to prevent the spread of contamination and minimize inhalation and ingestion of licensed materials and actions to obtain suitable radiation survey instruments, as required by **12VAC5-481-3200 B**.
- Instructions for the proper storage and disposal of radioactive waste
- Procedures for laundering contaminated clothing and for decontaminating equipment and vehicles
- Procedures to be followed in the event of uncontrolled release of radioactive tracer material to the environment, including notification of the RSO, the agency, and other state and federal agencies.

Discussion: The purpose of operating and emergency procedures is to provide well logging and tracer personnel, including field flood study personnel, with specific guidance for all operations they will perform. Each topic of importance should be included in the operating and emergency procedures and need not be presented in order. Instructions for non-routine operations, for example, inspection and maintenance of well logging and tracer equipment or conducting calibration of survey instruments, should be included as separate appendices in the application.

Operating and emergency procedures need not specify a particular make and model of survey instrument. Procedures should provide sufficient guidance and instruction for each specific type of well logging or associated equipment. For example, you may submit a single operating procedure for using sealed sources, tracer materials, and isotopes used in field flood operations, provided the unique variances in each operation are addressed in the application.

Operating and emergency procedures or a summary of the procedures that addresses the important radiation safety aspects of each must be submitted to the agency for review as a part of the application.

Response from Applicant:

Item 10.10 Operating and Emergency Procedures

☐ Operating and emergency procedures or an outline or summary as described in **12VAC5-481-3151** and **12VAC5-481-3280** have been attached for agency review.

Item 10.11 Transportation

Rule: 12VAC5-481-100, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-880, 12VAC5-481-960, 12VAC5-481-1060, 12VAC5-481-1080, 12VAC5-481-2980, 12VAC5-481-3000, 12VAC5-481-3010, 12VAC5-481-3070, 12VAC5-481-3130, 12VAC5-481-3170, 12VAC5-481-3180, 12VAC5-481-3190, 12VAC5-481-3250, 49 CFR Parts 171-178

Criteria: Applicants must develop, implement, and maintain safety programs for transport of radioactive material to ensure compliance with VDH and Department of Transportation (DOT) regulations.

Discussion: Licensees should consider the safety of all individuals who may either handle or come into contact with transport containers or packages containing licensed material. The primary consideration in packaging licensed material should be to ensure that the package integrity is not compromised during transport and that the radiation levels or removable contamination levels at the package surfaces meet the regulatory requirements of **12VAC5-481-3070** and **12VAC5-481-3190**.

In all cases, ALARA concerns are addressed prior to, during, and after transporting any radioactive material.

Note: Licensees shipping radioactive waste for disposal must prepare appropriate documentation as specified in **12VAC5-481-960** and **Appendix S.**

Discussion: Ensuring the radioactive materials are properly packaged in labeled containers that are braced and blocked, secured, and away from the driver while the shipping papers are kept in the cab with the driver illustrates some DOT requirements often overlooked by well logging, tracer, and field flood study licensees. During an inspection, the agency uses the provisions of **12VAC5-481-2980** and appropriate DOT regulations to examine and enforce transportation requirements applicable to well logging, tracer, and field flood study licensees. **Appendix S** lists major DOT regulations and provides a sample shipping paper.

Response from Applicant:

Item 10.11 Transportation
No response is needed from applicants during licensing phase. This matter will be examined during an inspection.

References: *"A Review of Department of Transportation Regulations for Transportation of Radioactive Materials (1983 revision)"* can be obtained be calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4425.

Item 11 Well Logging, Tracer, and Field Flood Study Operations

Item 11.1 Drill-to-Stop Large Sealed Sources

Rule: 12VAC5-481-3151, 12VAC5-481-3240, 12VAC5-481-3280, 12VAC5-481-3300, 12VAC5-481-3350, 12VAC5-481-3360, 12VAC5-481-3370

Criteria: Licensee must develop and follow instructions to be used by logging personnel when using licensed sealed radioactive sources in drill-to-stop well logging operations. Unlike measurement while drilling (MWD) or logging while drilling (LWD) operations where well logging operations occur concurrent with the drilling operations, drill-to-stop (DTS) well logging operations require that all drilling operations cease and that parts of the drilling apparatus, including all of the drill stem, be removed to provide access to the well bore. The well logging tool containing one or more sealed sources is then lowered into the well bore to obtain information about the well or adjacent oil, gas, mineral, groundwater, or geological formations.

Discussion: Operating and emergency procedures that cover the use of sealed sources in DTS well logging operations must be developed and implemented.

Applicants who request authorization to use sealed sources in DTS well logging operations in well bores without a surface casing should describe the procedures to be followed necessary to ensure that a sealed source does not become lodged in the well bore. Examples of acceptable procedures include:

- Obtaining specific knowledge of the borehole conditions from the drilling team or company
- First running a caliper log to show the hole is open or to find problem areas
- First running a tool without a radioactive source to show it can be freely removed
- Placing a temporary casing in sections of the hole giving problems.

Instructions in DTS well logging activities should include procedures for using appropriate remote handling tools for handling sealed sources. If only certain handling tools are to be used with particular sealed sources, instructions should clearly address which handling tool is required for each specific sealed source.

Response from Applicant:

Item 11.1 Drill-to-Stop Large Sealed Sources (Check box)
☐ We have submitted procedures for conducting Drill-to-Stop well logging operations or an outline or summary that addresses important radiation safety aspects in the operating and emergency procedures.

Item 11.2 Measurement While Drilling, Logging While Drilling

Rule: 12VAC5-481-3151, 12VAC5-481-3240, 12VAC5-481-3280, 12VAC5-481-3300, 12VAC5-481-3350, 12VAC5-481-3360, 12VAC5-481-3370

Criteria: Licensees must develop and follow procedures to be used by logging personnel when using licensed sealed radioactive sources in Measurement While Drilling (MWD) or Logging While Drilling (LWD) well logging operations. MWD or LWD well logging operations occur during the drilling of the well bore and do not require that the drill stem or other equipment be removed from the well. MWD or LWD requires that the well logging tool containing one or more sealed sources be located above the drilling stem to obtain information about the well or adjacent oil, gas, mineral, groundwater, or geological formations while the well drilling operation continues uninterrupted. Both MWD and LWD activities can be conducted at the same time drilling operations are occurring. Downhole recorded data from MWD or LWD sensors is transmitted to the surface through the use of mud telemetry.

Discussion: Operating and emergency procedures that cover the use of sealed sources in MWD or LWD well logging operations must be developed and implemented. Instructions in MWD and LWD well logging activities should include procedures for using appropriate remote handling tools for handling sealed sources. If only certain handling tools are to be used with particular sealed sources, instructions should clearly address which handling tool is required for each specific sealed source.

Response from Applicant:

Item 11.2 Measurement While Drilling, Logging While Drill (Check box)
☐ We have submitted procedures for conducting Measurement While Drilling, Logging While Drilling well logging operations or an outline or summary that addresses important radiation safety aspects in the operating and emergency procedures.

Item 11.3 Energy Compensation Sources

Rule: 12VAC5-481-500, 12VAC5-481-3151, 12VAC5-481-3210, 12VAC5-481-3220, 12VAC5-481-3230, 12VAC5-481-3240, 12VAC5-481-3280, 12VAC5-481-3350, 12VAC5-481-3360, 12VAC5-481-3370

Criteria: Energy compensation sources (ECSs) used in well logging operations are low-activity special form singly or doubly encapsulated sources containing less than or equal to 3.7 MBq (100 microcuries) of byproduct material. ECSs are used as reference or calibration standards for stabilizing and calibrating conventional, LWD, or MWD well logging tools.

Discussion: ECSs are not considered well logging sealed sources and are not required to satisfy the requirement for well logging sealed sources. As a result, ECSs are:

- Exempt, in most instances, from leak testing requirements, per **12VAC5-481-3210 E**, ECSs requiring leak testing must be tested at intervals not to exceed 3 years.
- Exempt from abandonment requirements when only ECSs less than or equal to 3.7 MBq (100 microcuries) remain in the abandoned tool.
- Exempt from the performance requirements of sealed sources used in well logging operations.
- Exempt from the monitoring requirements during source recovery operations when only ECSs less than or equal to 3.7 MBq (100 microcuries) remain in a well logging tool that is lodged in a well.
- Exempt from all requirements in **12VAC5-481, 'Virginia Radiation Protection Regulations', Part XIV, 'Radiation Safety Requirements for Wireline Service Operations and Subsurface Tracer Studies'**, with the exceptions of physical inventory and records of use. Requirements established in other parts of VDH regulations (e.g., **12VAC5-481, 'Virginia Radiation Protection Regulations', Part III** and **Part IV**) are still applicable to possession and use of byproduct material contained in ECSs.
- If a surface casing is not used to protect fresh water aquifers, see **12VAC5-481-3240 D** for applicable requirements.

Response from Applicant:

Item 11.3 Energy Compensation Sources (Check box)

☐ We will submit operating and emergency procedures for using and handling energy compensation sources.

OR

☐ We will submit an outline or summary of the operating and emergency procedures for using and handling energy compensation sources including instructions for leak testing energy compensation sources, if required, at intervals not to exceed 3 years, instructions for conducting physical inventories at least every 6 months, maintaining records of inventories required by **12VAC5-481-3220** and records of use for energy compensation sources.

OR

☐ We will submit alternative procedures for agency review.

OR

☐ Energy compensation sources will not be used.

Item 11.4 Use of Sealed Sources or Neutron Generators in Fresh Water Aquifers

Rule: 12VAC5-481-3241, 12VAC5-481-3280

Criteria: The licensee is prohibited from using sealed sources or neutron generators in fresh water aquifers unless the licensee requests and receives written permission from the agency.

Discussion: Use of radioactive materials in fresh water aquifers is a prohibited activity. Authorizing to use sealed sources or neutron generators in fresh water aquifers requires that operating and emergency procedures include the following information:

- Obtaining specific knowledge of the borehole conditions from the drilling team or company
- First running a caliper log to show the hole is open or to find problem areas
- First running a tool without a radioactive source to show it can be freely removed
- Placing a temporary casing in sections of the hole giving problems.

Response from Applicant:

Item 11.4 Use of Sealed Sources or Neutron Generators in Fresh Water Aquifers	
☐	We will not conduct this prohibited activity. OR
☐	We are requesting authorization for this prohibited activity and have included the required procedures as stated in 'Use of Sealed Sources or Neutron Generators in Fresh Water Aquifers' of VAREG 'Guidance for Well Logging, Tracer, and Field Flood Study'.

Item 11.5 Tracer Studies in Single Well Applications

Rule: 12VAC5-481-640, 12VAC5-481-720, 12VAC5-481-750, 12VAC5-481-840, 12VAC5-481-900, 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1161, 12VAC5-481-2980, 12VAC5-481-3190, 12VAC5-481-3200, 12VAC5-481-3260, 12VAC5-481-3280, 12VAC5-481-3290, 12VAC5-481-3320, 12VAC5-481-3340, 12VAC5-481-3350, 12VAC5-481-3360, 12VAC5-481-3370

Criteria: Applicants must develop, implement, and maintain safety programs for the use of unsealed material for tracer studies in single wells.

Discussion: Applicants' operating and emergency procedures should address the following concerns:

- Methods and occasions for conducting radiation surveys
- Methods and occasions for locking and securing tracer materials
- Personnel monitoring and the use of personnel monitoring equipment
- Transportation to temporary job sites and field stations, including the packaging and placing of tracer materials in vehicles, placarding of vehicles, and securing of tracer materials during transportation
- Procedures for minimizing exposure to members of the public and occupationally exposed individuals in the event of an accident
- Maintenance of records at field stations and temporary job sites
- Use, inspection, and maintenance of equipment (injector tools, remote handling tools, transportation containers, etc.)
- Procedures to be used for picking up, receiving, and opening packages containing radioactive material
- Decontamination of the environment, equipment, and personnel
- Notifications of proper personnel in the event of an accident.

Response from Applicant:

Item 11.5 Tracer Studies in Single Well Applications
No response is required for this section provided that the elements in the 'Tracer Studies in Single Well Applications' of VAREG 'Guidance for Well Logging, Tracer, and Field Flood Study' are contained in other sections.

Item 11.6 Field Flood and Secondary Recovery Applications (Tracer Studies in Multiple Wells)

Rule: 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-570, 12VAC5-481-640, 12VAC5-481-720, 12VAC5-481-840, 12VAC5-481-900, 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1150, 12VAC5-481-1161, 12VAC5-481-2980, 12VAC5-481-3151, 12VAC5-481-3160, 12VAC5-481-3260, 12VAC5-481-3280, 12VAC5-481-3290, 12VAC5-481-3300, 12VAC5-481-3320, 12VAC5-481-3340, 12VAC5-481-3350, 12VAC5-481-3360, 12VAC5-481-3370

Criteria: Applicants must develop, implement, and maintain safety programs for the use of unsealed material for tracer studies in multiple wells (field flood studies). Refer to **Appendix F** in developing step-by-step instructions for tracer personnel in performing field flood tracer studies for multiple wells. Field flood study activities where licensed material is intentionally released into the environment require an environmental assessment (EA) in accordance with the provisions of appropriate United States Code of regulation.

Reference: NUREG/CR-3467, *"Environmental Assessment of the Use of Radionuclides as Tracers in the Enhanced Recovery of Oil and Gas"*, dated November 1983. For copies of NUREG/CR-3467, available at the NRC website: http://www.nrc.gov.

Discussion: Applicants should address the following when requesting field flood and secondary recovery applications:

- Agreement with well operator or owner
- Field flood study project design
- Pre-injection phase of the field flood project
- Injection phase
- Post-injection phase
- Emergency procedures
- Reporting and record keeping requirements
- Waste management
- Methods and occasions for conducting radiation surveys
- Methods and occasions for locking and securing tracer materials
- Personnel monitoring and the use of personnel monitoring equipment
- Transportation to temporary job sites and field stations, including the packaging and placing of tracer materials in vehicles, placarding of vehicles, and securing tracer materials during transportation
- Procedures for minimizing exposure to members of the public and occupationally exposed individuals in the event of an accident
- Maintenance of records at field stations and temporary job sites
- Use, inspection, and maintenance of equipment (injector tools, remote handling tools, transportation containers, etc.)

- Procedures to be used for picking up, receiving, and opening packages containing radioactive material
- Decontamination of the environment, equipment, and personnel
- Notifications of proper personnel in the event of an accident.

Response from Applicant:

Item 11.6 Field Flood and Secondary Recovery Applications (Tracer Studies in Multiple Wells)
☐ Field flood studies using tracer materials will not be conducted unless authorized specifically by license conditions. OR
☐ We are requesting authorization to conduct field flood studies in the enhanced recovery of oil and gas wells using the information provided in Appendix F of the VAREG 'Guidance for Well Logging, Tracer, and Field Flood Study'.

Item 11.7 Tracer Studies in Fresh Water Aquifers

Rule: 12VAC5-481-3320

Criteria: Applicants must develop, implement, and maintain a safety program for using tracer materials in fresh water aquifers. Licensees may not knowingly inject licensed material into a freshwater aquifer unless specifically authorized to do so by the VDH license.

Discussion: VDH, in accordance with **12VAC5-481-3320 B**, prohibits the intentional injection of licensed tracer material into a fresh water aquifer unless the individual is specifically authorized by the license to perform this activity. VDH staff position concerning the intentional injection of licensed tracer material authorized under **12VAC5-481, 'Virginia Radiation Protection Regulations', Part XIV, 'Radiation Safety Requirements for Wireline Service Operations and Subsurface Tracer Studies'** into a fresh water aquifer requires the preparation of an environmental report by the licensee or applicant. Well logging applicants and applicants requesting field flood studies should refer to the appropriate United States Code (**10 CFR Part 51.45**) and prepare an environmental report. Authorizing an applicant to conduct tracer studies in accordance with **12VAC5-481, 'Virginia Radiation Protection Regulations', Part XIV, 'Radiation Safety Requirements for Wireline Service Operations and Subsurface Tracer Studies'** in fresh water aquifers would require NRC's assessment of an environmental report and a "*finding of no significant impact*" by the NRC staff.

Authorizing field flood studies that require the applicant to intentionally inject licensed tracer material into a fresh water aquifer would require that an environmental report be prepared by the applicant and an environmental assessment be made by an authorized party.

NRC specifies the criteria for categorical exclusions. When one or more of the criteria for a categorical exclusion are satisfied, the applicant or licensee is relived from the requirements for preparing an environmental impact statement. This then relieves the requirement of preparing an environmental assessment prior to the issuance, amendment, or renewal of licenses authorizing the use of radioactive tracers in well logging procedures authorized under **12VAC5-481, 'Virginia Radiation Protection Regulations', Part XIV, 'Radiation Safety Requirements for Wireline Service Operations and Subsurface Tracer Studies'**. However, the intentional release of licensed radioactive material directly to the environment as a result of a research or other study is not categorically excluded. NRC specifies in that in special circumstances or on the request of any interested individual or party, an environmental assessment on an action normally covered by a categorical exclusion could be required.

Note: NRC's completion of an environmental assessment, based on the level of complexity, can require several months to review, approve, and publish in the Federal Register for comments.

Response from Applicant:

Item 11.7 Tracer Studies in Fresh Water Aquifers

☐ We will not knowingly inject tracer material into a fresh water aquifer.

OR

☐ We are requesting authorization to inject licensed radioactive materials into a fresh water aquifer and are providing the reason(s) for this study and procedures to protect the worker(s) and the public.

Note: Tracer and field flood studies require an environmental report.

Radioactive Markers

Item 11.8 Radioactive Collar and Subsidence or Depth Control Markers

Rule: 12VAC5-481-3220, 12VAC5-481-3261, 12VAC5-481-3280, 12VAC5-481-3730

Criteria: Radioactive markers usually used as pipe collar markers include wires, tape, nails, etc. Applicants can use radioactive markers only where each individual marker contains quantities of licensed material not exceeding the quantities identified in **12VAC5-481-3730**. Radioactive markers must be physically inventoried at intervals not to exceed 6 months, as specified in **12VAC5-481-3220**.

Discussion: Operating and emergency procedures must include a commitment that radioactive markers can be used only where each individual marker contains quantities of licensed material not exceeding the quantities identified in **12VAC5-481-3730**. However, licensees are not restricted to using only one marker, and may use multiple markers in each pipe joint, provided each individual marker (wires, tape, nails, etc.) is not greater than the quantities identified in **12VAC5-481-3730**. Additionally, provisions must be included in the operating and emergency procedures to ensure that radioactive markers undergo physical inventories at intervals not to exceed 6 months, as specified in **12VAC5-481-3220**.

Note: Subsidence or depth control markers that use quantities greater that those authorized by **12VAC5-481-3261** must be approved or registered by the VDH, NRC or another Agreement State in an SSD Registration Certificate.

Response from Applicant:

Item 11.8 Radioactive Collar and Subsidence or Depth Control Markers

☐ We will only use radioactive markers where each individual marker contains only quantities of licensed material not exceeding the quantities identified in **12VAC5-481-3730**.

OR

☐ We have submitted procedures for using radioactive markers that in excess of quantities listed in **12VAC5-481-3730**.

Item 11.9 Neutron Accelerators using Licensed Material

Rule: 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-780, 12VAC5-481-790, 12VAC5-481-3241, 12VAC5-481-3280, 12VAC5-481-3340

Criteria: Applicants authorized to use a neutron generator (particle accelerator) containing a tritium source, should include operating and emergency procedures for the proper handling and use of the accelerator targets or tubes containing radioactive materials.

Discussion: Neutron generators (accelerators) are used in the well logging industry as a source of neutrons. Most accelerators use tritium gas sealed in a glass tube or plated on a target or disc. Neutron generator target sources, in most instances, contain less than 1,110 GBq (30 curies) of tritium.

Neutron generator tubes are not considered well logging sealed sources and are not required to satisfy the requirement for well logging sealed sources. As a result, neutron generator tubes containing less than 1,110 GBq (30 curies) of tritium are:

- Exempt from abandonment requirements
- Exempt from leak test requirements
- Exempt from the performance requirements of sealed sources used in well logging operations
- Not exempt if a tritium neutron generator for target source is greater than 1,110 GBq (30 curies) or is used in a well without a surface casing to protect fresh water aquifers.

Applicants using a neutron generator (particle accelerator) should include handling procedures that address contamination. Operating and emergency procedures should instruct individuals in the handling of contamination resulting from the routine use, initial installation, replacement, or accidental damage of the targets or glass tubes. Refer to **12VAC5-481-3241** for applicable requirements for using neutron generators.

Response from Applicant:

Item 11.9 Neutron Accelerators using Licensed Material (Check box)

☐ We will not use neutron generators (accelerators) in our well logging operations.

OR

☐ We will use neutron generators (accelerators) in accordance with the criteria in 'Neutron Accelerators using Licensed Material' of VAREG 'Guidance for Well Logging, Tracer, and Field Flood Study'.

Item 11.10 Depleted Uranium Sinker Bars

Rule: 12VAC5-481-420, 12VAC5-481-570, 12VAC5-481-3250, 12VAC5-481-3260, 12VAC5-481-3340

Criteria: Depleted uranium sinker bars are both generally licensed and specifically licensed. Most well logging licensees acquire depleted uranium sinker bars under the provisions of **12VAC5-481-420 C** and then file VDH form, 'Registration Certificate — Use of Depleted Uranium Under General License'. Specifically licensed material must be physically inventoried and visually inspected for labeling and physical damage.

Discussion:

Depleted Uranium Sinker Bars Authorized Under General License:
Certain devices are authorized by VDH for distribution to persons who are generally licensed for the use of certain industrial products or devices containing depleted uranium for the purpose of providing a concentrated mass in a small volume. Uranium sinker bar devices can be acquired by the users under the provisions of **12VAC5-481-420 C** without obtaining a specific license from VDH; however, when acquired under the provisions of a general license, individuals must file VDH form, 'Registration Certificate — Use of Depleted Uranium Under General License'.

Generally licensed sinker bars are exempt from **12VAC5-481, 'Virginia Radiation Protection Regulations', Part IV** and **Part X**. Regulatory requirements that apply to such devices possessed under a general license are stated in **12VAC5-481-420 C**. While operating under the provision of a general license for these types of devices, general licensees must:

- Not introduce uranium sinker bars into a chemical, physical, or metallurgical treatment or process, except as a treatment for restoration of any plating or covering
- Not abandon uranium sinker bars
- Transfer only to individuals authorized under the provisions of **12VAC5-481-570**
- Notify the agency within 30 days of the transfer of depleted uranium sinker bars.

Depleted Uranium Sinker Bars Authorized under a Specific License:
While operating under the provision of a specific license for these types of devices, specific licensees must:

- Physically inventory the uranium sinker bars at intervals not to exceed 6 months.
- Visually inspect before use for proper labeling, "*CAUTION RADIOACTIVE DEPLETED URANIUM*" and "*NOTIFY CIVIL AUTHORITIES (or COMPANY NAME) IF FOUND*", at intervals not to exceed 6 months.
- Visually inspect for physical damage and conduct routine maintenance at intervals not to exceed 6 months, as specified in **12VAC5-481-3260**.
- Remove bars from use if found defective, until repaired or disposed.
- Record information specified in **12VAC5-481-3260**.

Response from Applicant:

Item 11.10 Depleted Uranium Sinker Bars (Check box)

☐ Depleted uranium sinker bars will be obtained under the provisions of a general license (**12VAC5-481-420 C**) and the appropriate VDH form will be filed, as required.

OR

☐ Depleted uranium sinker bars will not be obtained under the provisions of a general license (**12VAC5-481-420 C**).

AND

Uranium sinker bars will be possessed and inspected as specified in **12VAC5-481-3260**.

AND

We wish to request _____ kilograms of materials

OR

☐ Depleted uranium sinker bars will not be used.

Item 12: Waste Management

Rule: 12VAC5-481-100, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-840, 12VAC5-481-880, 12VAC5-481-910, 12VAC5-481-920, 12VAC5-481-930, 12VAC5-481-940, 12VAC5-481-950, 12VAC5-481-960, 12VAC5-481-970, 12VAC5-481-971, 12VAC5-481-1060, 12VAC5-481-1890, 12VAC5-481-2571, 12VAC5-481-2572, 12VAC5-481-2980, 12VAC5-481-3690

Criteria: Radioactive waste must be disposed of in accordance with regulatory requirements and license conditions and/or transferred to an authorized recipient. Authorized recipients are the original manufacturer, distributor, a commercial firm licensed by VDH, NRC, or another Agreement State to accept radioactive waste from other persons, or in the case of sealed sources, transferred to another specific licensee authorized to possess the licensed material (i.e., a transferees' license specifically authorizes the same radionuclide, chemical or physical form, and in most instances, the same use). Records of transfer and waste disposal must be maintained per **12VAC5-481-1060**.

Before transferring any radioactive material, including radioactive waste, a licensee must verify that the recipient is properly authorized to receive the specific type of material using one of the methods described in **12VAC5-481-570**. In addition, all packages containing radioactive waste must be prepared and shipped in accordance with VDH and DOT regulations. Records of transfer and disposal must be maintained as required by **12VAC5-481-100** and **12VAC5-481-571**.

Discussion: Radioactive waste generated when conducting licensed activities may include: sealed sources, used or unused radioactive tracer materials, and unusable items contaminated with radioactive tracer materials (e.g., absorbent paper, gloves, bottles, etc.). Unsealed radioactive waste must be stored in strong, tight containers (e.g., thick plastic bags, boxes, barrels, etc.) to prevent the spread of contamination, and sealed sources should be stored in their corresponding transport containers or in a downhole storage bunker until their disposal.
The integrity of the radioactive waste containers must be assured, and the containers, while in storage, must have the appropriate warning label specified in **12VAC5-481-880**. Radioactive waste must be secured against unauthorized access or removal. Depending on the radioactive half-life of the material, VDH requires disposal of well logging sealed sources and tracer materials generated at licensees' facilities by one or more of the following methods:

Tracer Material with a Half-Life of 120 Days or Less:

- Decay-in-storage (DIS)
- Transfer to an authorized recipient
- Release into sanitary sewerage
- Obtaining prior approval from VDH of any alternate method
- Release in effluents to unrestricted areas, other than into sanitary sewerage
- Incineration.

Tracer Material with a Half-Life Greater Than 120 Days:

- Transfer to an authorized recipient
- Release into sanitary sewerage
- Extended interim storage
- Obtaining prior approval from VDH of any alternate method
- Release in effluents to unrestricted areas, other than into sanitary sewerage
- Incineration.

Sealed Sources with a Half-Life of 120 Days or Less:

- Transfer to an authorized recipient
- DIS
- Extended interim storage.

Sealed Sources with a Half-Life Greater Than 120 Days:

- Transfer to an authorized recipient.

Licensees may choose any one or more of these methods to dispose of their radioactive waste. The agency's experience indicates that most well logging tracers are stored or disposed of by a combination of methods, transfer to an authorized recipient and DIS being the most frequently used. Applicants requesting authorization to dispose of radioactive tracer waste by incineration should first refer to NRC's Policy and Guidance Directive PG 8-10, *"Disposal of Incinerator Ash as Ordinary Waste"*, dated January 1997, for guidance. Applicants should note that compliance with VDH regulations does not relieve them of their responsibility to comply with any other applicable local, state, or federal regulations. Some types of radioactive waste used in tracer operations and in 'labeled frac sands' may include additional chemical hazards. This type of waste is designated as 'mixed waste' and requires special handling and disposal.

Applicants should describe in detail their program for management and disposal of radioactive waste, including mixed waste, if applicable. A waste management program should include procedures for handling waste; specify the requirements for safe and secure storage; and describe how to characterize, minimize, and dispose of all types of radioactive waste, including, where applicable, mixed waste. Appropriate training should be provided to waste handlers. **12VAC5-481-1060** requires, in part, 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 as a contaminant. 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 with a half-life of 120 days or less. 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 with physical half-lives 120 days or less may be segregated and stored in a container and allowed to decay for at least ten half-lives based on the longest-lived radioisotope in the container. Waste management procedures should include: methods of segregating waste by physical half-lives of 120 days or less, greater than 120 days, methods of surveying waste prior to disposal to confirm that waste above background levels is not inadvertently released, and maintenance of records of disposal. Disposal records for DIS should include the date when the waste was put in storage for decay, date when ten half-lives of

the longest-lived radioisotope had transpired, date of disposal, and results of final survey taken prior to disposal as ordinary trash. Additionally, a model procedure for disposal of radioactive waste by DIS, which incorporates the above guidelines, is provided in **Appendix T**.

Release Into Sanitary Sewerage

12VAC5-481-930 authorizes disposal of radioactive waste by release into sanitary sewerage 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 **12VAC5-481-3690**, Table 3 of reference.
- If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit in **12VAC5-481-3690**, Table 3 (of reference) cannot exceed unity
- 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 sewerage system are indeed readily dispersible 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 the criteria for evaluating solubility of liquid waste. Careful consideration should be given to the possibility of re-concentration of radioisotopes that are released into the sewer. NRC alerted licensees to the potentially significant problem of re-concentration of radionuclides released to sanitary sewerage systems in NRC IN 84-94, *"Reconcentration of Radionuclides InvolvingDischarges into Sanitary Sewerage Systems Permitted Under 10 CFR 20.203 (now 10 CFR 20.2003)"*, dated December 1984.

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

Note: 12VAC5-481, 'Virginia Radiation Protection Regulations' prohibits the disposal of radioactive materials via a sewage treatment facility, septic system, or leach field owned or operated by the licensee.

Transfer to an Authorized Recipient

Licensees may transfer radioactive waste to an authorized recipient for disposal. However, it is the licensee's responsibility to verify that the intended recipient is authorized to receive the radioactive waste prior to making any shipment. Waste generated at well logging and tracer facilities generally consists of low specific activity (LSA) material. The waste must be packaged in DOT-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 requirements. Each shipment must comply with all applicable VDH and DOT requirements. In some cases, the waste handling contractor may provide additional guidance and requirements to licensees for packaging and transportation; however, the licensee is ultimately responsible for ensuring compliance with all applicable regulatory requirements.

The shipper must provide all information required in VDH form, 'Uniform Low-Level Radioactive Waste Manifest' and transfer this recorded manifest information to the intended recipient. Each shipment manifest must include a certification by the waste generator. 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 NRC's Uniform Low-Level Radioactive Waste Manifest.

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.

Applicants may request alternate methods for the disposal of radioactive waste generated at their facilities. Such requests will be handled on a case-by-case basis and require that the applicant provide additional site-specific information. In most instances, requests for alternate methods of disposal must describe the types and quantities of waste containing licensed material, physical and chemical properties of the waste that may be important to making a radiological risk assessment, and the proposed manner and conditions of waste disposal. Additionally, the applicant must submit its analysis and evaluation of pertinent information specific to the affected environment, including the nature and location of other affected facilities, and provide an outline of its procedures to ensure that radiation doses are maintained ALARA and within VDH limits. Because of the difficulties and costs associated with disposal of sealed sources (e.g., sealed sources containing Americium-241) applicants should preplan disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement.

Extended Interim Storage

Prior to requesting extended interim storage of radioactive waste materials, and this only as a last resort, licensees should exhaust all possible alternatives for disposal of radioactive waste. The protection of occupationally exposed workers or the public is enhanced by disposing of radioactive waste, rather than storing it. In addition, licensees may find it more economical to dispose of radioactive waste than to store it on-site. As available burial ground capacity decreases, cost of disposal of radioactive waste most likely will 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 and NRC IN 93-50, *"Extended Storage of Sealed Sources"*, dated July 1993, provides guidance to VDH licensees for requesting an amendment to authorize extended interim storage of both sealed and unsealed LLW.

Response from Applicant:

Item 12 Waste Management
☐ We will use Appendix T of VAREG 'Guidance for Well Logging, Tracer, and Field Flood Study'.
OR
☐ We will use Decay-In-Storage model waste procedure in Appendix T of VAREG, 'Guidance for Well Logging, Tracer, and Field Flood Study'.
AND/OR
☐ We will use Disposal of Liquids Into Sanitary Sewage (**12VAC5-481-930**) model waste procedure in Appendix T of VAREG, 'Guidance for Well Logging, Tracer, and Field Flood Study'.
OR
☐ We have attached our procedures for waste collection, storage, and disposal by any of the authorized methods and request authorization for the methods described.

Note: Applicants do not need to provide information to the agency if they plan to dispose of LLW via transfer to an authorized recipient. Alternative responses will be reviewed using the criteria listed above.

References: A copy of all of the below is available on the NRC's website at: http://www.nrc.gov.

1. NRC Policy and Guidance Directive PG 8-10, "*Disposal of Incinerator Ash as Ordinary Waste*", dated January 1997
2. NRC Policy and Guidance Directive PG 94-05, "*Updated Guidance on Decay-In-Storage*", dated October 1994
3. NRC Information Notice 94-23, "*Guidance to Hazardous, Radioactive, and Mixed Waste Minimization Program*", dated May 1994
4. NRC Information Notice 94-07, "*Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20*", dated January 1994
5. NRC Information Notice 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
6. NRC Information Notice 90-09, "*Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees*", dated February 1990
7. NRC Information Notice 93-50, "*Extended Storage of Sealed Sources*", dated July 1993.

Item 13: License Fees

Rule: 12VAC5-490

Criteria: On VDH form, 'Application for a Radioactive Material License Authorizing the Use of Sources in Well Logging, Tracer, and Field Flood Study', enter the appropriate fee category from **12VAC5-491** and the amount of the fee enclosed with the application.

Note: Applicants who wish to perform field flood tracer studies should review the applicable United States Code regulation for further information concerning the environmental information needed to prepare an environmental assessment.

Response from Applicant:

Item 13 License Fees (Refer to **12VAC5-490.**)	
Category:	Application Fee Enclosed (For new applications): ☐ Yes ☐ No Amount Enclosed $_____

Item 14: Certification

Individuals acting in a private capacity are required to date and sign VDH form, 'Application for a Radioactive Material License Authorizing the Use of Sources in Well Logging, Tracer, and Field Flood Study'. Otherwise, representatives of the corporation or legal entity filing the application should date and sign VDH form, 'Application for a Radioactive Material License Authorizing the Use of Sources in Well Logging, Tracer, and Field Flood Study'. Representatives signing an application must be authorized to make binding commitments and to 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 agency will return all unsigned applications for proper signature.

Note:

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

Response from Applicant:

CERTIFICATION (To be signed by an individual authorized to make binding commitments on behalf of the applicant.)	
Item 14 I hereby certify that this application was prepared in conformance with **12VAC5-481, '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 A

VDH Form, 'Application for a Radioactive Material License Authorizing the Use of Material in Well Logging, Tracer, and Field Flood Study'

VIRGINIA DEPARTMENT OF HEALTH
Radioactive Materials Program
109 Governor Street, Room 730
Richmond, VA 23219
(804) 864-8150

APPLICATION FOR A RADIOACTIVE MATERIAL LICENSE AUTHORIZING THE USE OF MATERIAL IN WELL LOGGING, TRACER, AND FIELD FLOOD STUDY

The Virginia Department of Health (VDH) is requesting disclosure of all information 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 Well Logging, Tracer and Field Flood Study'. 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 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):

LOCATION OF RADIOACTIVE MATERIAL

Item 4 Location of Radioactive Material (Do not use Post Office Box):

(Attach additional pages if necessary)

☐ Used ☐ Stored ☐ Used and Stored	Address: , -	Telephone Number (Include area code): ( ) -
☐ Used ☐ Stored ☐ Used and Stored	Address: , -	Telephone Number (Include area code): ( ) -
☐ Used ☐ Stored ☐ Used and Stored	Address: , -	Telephone Number (Include area code): ( ) -

Are devices going to be used and/or stored at field stations? ☐ Yes ☐ No

Are devices going to be used and/or stored at temporary jobsites?: ☐ Yes ☐ No

If yes, check the following boxes:

☐ We will perform and maintain documentation of radiation surveys to ensure that radiation levels are less than 2 mrem in any one hour and 100 mrem/yr at all temporary job site storage locations.

☐ We will store the device at the temporary job site in a locked room, trailer or other secure location to prevent unauthorized removal of the device.

☐ We will minimize exposures for occupational and non-occupational workers when selecting storage location.

☐ We will limit storage at a temporary job site to 180 days per calendar year.

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

☐ 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.

NAME: TELEPHONE NUMBER (Include area code):

AND

☐ We will demonstrate that the RSO has sufficient independence and direct communication with responsible management officials by providing a copy of an organizational chart by position and will confirm that the RSO has day-to-day oversight of the radiation safety activities.

AND EITHER

☐ We have included documentation showing the RSO's qualifications and experience.

OR

☐ We will provide alternative information demonstrating that the proposed RSO is qualified by training and experience (e. g., listed by name as an authorized user or the RSO on an VDH, NRC, or another Agreement State license that requires a radiation safety program of comparable size and scope) documentation to show that the RSO has obtained formal training in the establishment and maintenance of a radiation protection program.

TRAINING FOR LOGGING SUPERVISORS AND LOGGING ASSISTANTS

Item 6 Training For Logging Supervisors, Logging Assistants, and Tracer/Field Flood Study Users (Check box and attach requested information)

☐ We will submit an outline of the training to be given to prospective logging supervisors and logging assistants and have enclosed our procedures training given to experienced logging supervisors. We have also submitted a typical examination given, the correct answers to the questions and the passing grade.

AND

☐ We have included the qualifications of our instructors and their experience with well logging activities or have included the course title, name, course outline (if available), address and telephone number of the company who will provide training.

AND

☐ We have submitted a description of the field examination given to prospective logging supervisors and assistants.

AND

☐ We have submitted an description of our program including the annual refresher training including the topics and how they will be covered and the inspection of each logging supervisor and logging assistants job performance, as described in 12VAC5-481-3150 A.

RADIOACTIVE MATERIAL

Item 7 Radioactive Material (Attach additional pages if necessary) Include sealed sources activity greater than 3.7 MBq (100 μCi)

Element and mass number	Sealed source manufacturer and model number
Maximum activity per source	Source changer manufacturer and model number
Are unsealed tracer materials used? ☐ Yes (complete below information) ☐ No	
Element name and mass number	Chemical/physical form
Maximum activity per tracer material: Maximum amount per study by physical/chemical form:	If volatile, anticipated rate of volatility or dispersion Intended Use
Are energy compensation sources used? ☐ Yes (complete below information) ☐ No	
Element name and mass number	Manufacturer's name and model number
Intended Use:	

FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING

Item 8 Financial Assurance And Recordkeeping For Decommissioning (Check both boxes)

☐ We shall maintain drawings and records important to decommissioning and will transfer these records to a new licensee before licensed activities are transferred in accordance with **12VAC5-481-510 B** or assign the records to the agency before the license is terminated.

AND

☐ If financial assurance is required, submit evidence per **12VAC5-481-450 C**.

FACILITIES AND EQUIPMENT

Item 9 Facilities And Equipment (Check box and attach requested information)

☐ We will submit the required information as listed in the section titled 'Facilities and Equipment' of VAREG 'Guidance for Well Logging, Tracer, and Field Flood Study'.

RADIATION SAFETY PROGRAM

Item 10 Radiation Safety Program (Check box)

☐ We have included our radiation safety program for agency review.

Item 10.1 Well Owner/Operator Agreement

☐ We will obtain a written agreement prior to commencement of operating any well logging operation with a sealed source as specified in **12VAC5-481-3160**.

Item 10.2 Radiation Safety Audit Program

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

Item 10.3 Termination of Activities (Check box)

☐ We will notify VDH, in writing, within 60 days of the decision to permanently cease radioactive material use (**12VAC5-481-510**).

Item 10.4 Radiation Monitoring Instruments (Check all boxes that apply)

☐ We will possess and use radiation survey meter(s) that meets the Criteria in the section titled 'Radiation Monitoring Instruments' in VAREG 'Guidance for Well Logging, Tracer, and Field Flood Studies'. We reserve the right to upgrade our survey instruments as necessary.

AND EITHER

☐ If calibration is performed by a person or firm outside the applicant's organization, the calibration will be performed by a VDH, NRC or another Agreement State licensee specifically authorized to perform instrument calibration.

OR

☐ We will follow the survey meter calibration procedures in accordance with Appendix N in VAREG 'Guidance for Well Logging, Tracer, and Field Flood Study'.

OR

☐ We will submit alternate procedures. (Procedures are attached)

Note: Identify the qualifications of the individuals who will perform the calibrations if performed by the applicant.

Item 10.5 Material Receipt And Accountability (Check box)

☐ Semi-annual physical inventories will be conducted of all licensed material, including byproduct, tracer materials, and depleted uranium and the information contained in the discussion section titled 'Material Receipt and Accountability' in VAREG 'Guidance for Well Logging, Tracer, and Field Flood Studies' will be documented.

Item 10.6 Leak Tests (Check one box)

☐ 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 the licensee 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 tests (specify whether VDH, NRC or another Agreement State)

Organization Name License Number Issuing Entity

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, the NRC or another Agreement State.

OR

☐ We will perform our own leak testing and sample analysis. We will follow the procedures in Appendix R of VAREG 'Guidance for Well Logging, Tracer, and Field Flood Study'.

OR

☐ We will submit alternative procedures. (Procedures are attached)

Item 10.7 Occupational Dosimetry (Check all boxes that apply)

☐ We will provide required dosimetry (film badge, TLD) that will be processed and evaluated by a NVLAP-approved processor that is exchanged monthly or quarterly, as appropriate, and worn by well logging personnel.

AND/OR

☐ We will provide a bioassay program when using unsealed tracer materials.

OR

☐ We will provide a commitment that no individual will use more than 50 millicuries of iodine-131 at any one time or in any 5-day period at field stations or temporary job sites.

Note: If intend to use an excess of amounts described or request permission to repackage or process iodine-131 tracer materials at field stations, it is necessary to describe in detail the bioassay program

OR

☐ We will contract a vendor for bioassay services who is licensed or otherwise authorized by VDH, NRC, or another Agreement State to provide required bioassay services.

Item 10.8 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 10.9.1 Daily Maintenance (Check both boxes)

☐ We have included procedures for conducting daily visual inspection.

OR

☐ Visual daily inspection will be conducted and records maintained in accordance with the criteria listed in 'Daily Maintenance' of the VAREG 'Guidance for Well Logging, Tracer, and Field Flood Study' to ensure that well logging equipment is in good working condition and is labeled as required.

Item 10.9.2 Semi-Annual Visual Inspection and Routine Maintenance (Check both boxes)

☐ We have included procedures for semi annual visual inspection and routine maintenance of source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars to ensure that the labeling required by **12VAC5-481-3250** is legible and that no physical damage is visible.

AND

☐ Semiannual inspections and routine maintenance will be conducted and records maintained for source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars in accordance with the criteria in 'Semi-Annual Visual Inspection and Routine Maintenance' of VAREG 'Guidance for Well Logging, Tracer, Field Flood Study' to ensure that well logging equipment is in good working condition with no physical damage evident and that required labeling is present.

Item 10.9.3 Maintenance Requiring Special Authorization (Check both boxes)

☐ Prohibited activities described in 'Maintenance Requiring Special Authorization' of VAREG 'Guidance for Well Logging, Tracer, Field Flood Study' will not be conducted unless approved by the agency.

OR

☐ Submit detailed procedures of each different tasks (including source removal procedures) for any prohibited activities, including radiation safety precautions that individuals will be expected to follow when performing these tasks and the minimum qualifications of these individuals.

Item 10.10 Operating and Emergency Procedures

☐ Operating and emergency procedures or an outline or summary as described in **12VAC5-481-3150 A 3** have been attached for agency review.

Item 10.11 Transportation

No response is needed from applicants during licensing phase. This matter will be examined during an inspection.

WELL LOGGING, TRACER, AND FIELD FLOOD STUDY OPERATIONS

Item 11. Well Logging, Tracer, and Field Flood Study Operations

Item 11.1 Drill-to-Stop Large Sealed Sources (Check box)

☐ We have submitted procedures for conducting Drill-to-Stop well logging operations or an outline or summary that addresses important radiation safety aspects in the Operating and Emergency procedures.

Item 11.2 Measurement While Drilling, Logging While Drill (Check box)

☐ We have submitted procedures for conducting Measurement While Drilling, Logging While Drilling well logging operations or an outline or summary that addresses important radiation safety aspects in the Operating and Emergency procedures.

Item 11.3 Energy Compensation Sources (Check box)

☐ We have submitted operating and emergency procedures for using and handling energy compensation sources.

OR

☐ We have submitted an outline or summary of the operating and emergency procedures for using and handling energy compensation sources including instructions for leak testing energy compensation sources, if required, at intervals not to exceed 3 years, instructions for conducting physical inventories at least every 6 months, maintaining records of inventories required by **12VAC5-481-3220** and records of use for energy compensation sources.

OR

☐ We have submitted alternative procedures for agency review.

OR

☐ Energy compensation sources will not be used

Item 11..4 Use of Sealed Sources or Neutron Generators in Fresh Water Aquifers (Check box)

☐ We will not conduct this prohibited activity.

OR

☐ We are requesting authorization for this prohibited activity and have included the required procedures as stated in 'Use of Sealed Sources or Neutron Generators in Fresh Water Aquifers' of VAREG, 'Guidance for Well Logging, Tracer, and Field Flood Study'.

Item 11.5 Tracer Studies in Single Well Applications (Check box)

No response is required for this section provided that the elements in the 'Tracer Studies in Single Well Applications' of VAREG 'Guidance for Well Logging, Tracer, and Field Flood Study' are contained in other sections.

Item 11.6 Field Flood and Secondary Recovery Applications (Tracer Studies in Multiple Wells) (Check box)

☐ Field flood studies using tracer materials will not be conducted unless authorized specifically by license conditions.

OR

☐ We are requesting authorization to conduct field flood studies in the enhanced recovery of oil and gas wells using the information provided in Appendix F of the VAREG 'Guidance for Well Logging, Tracer, and Field Flood Study'.

Item 11.7 Tracer Studies in Fresh Water Aquifers (Check box)

☐ We will not knowingly inject tracer material into a fresh water aquifer.

OR

☐ We are requesting authorization to inject licensed radioactive materials into a fresh water aquifer and are providing the reason(s) for this study and procedures to protect the worker(s) and the public.

Note: Tracer and field flood studies require an environmental report.

Item 11.8 Radioactive Collar and Subsidence or Depth Control Markers (Check box)

☐ We will only use radioactive markers where each individual marker contains only quantities of licensed material not exceeding the quantities identified in **12VAC5-481-3730**.

OR

☐ We have submitted procedures for using radioactive markers that in excess of quantities listed in **12VAC5-481-3730**.

Item 11.9 Neutron Accelerators using Licensed Material (Check box)

☐ We will not use neutron generators (accelerators) in our well logging operations.

OR

☐ We will use neutron generators (accelerators) in accordance with the criteria in 'Neutron Accelerators using Licensed Material' of VAREG 'Guidance for Well Logging, Tracer, and Field Flood Study'.

Item 11.10 Depleted Uranium Sinker Bars (Check box)

☐ Depleted uranium sinker bars will be obtained under the provisions of a general license (**12VAC5-481-420 C**) and the appropriate VDH form will be filed, as required.

OR

☐ Depleted uranium sinker bars will be possessed and inspected as specified in **12VAC5-481-3260**.

AND

Uranium sinker bars will be possessed and inspected as specified in **12VAC5-481-3260**

AND

We request _____ kilograms of material.

OR

☐ Depleted uranium sinker bars will not be used.

WASTE MANAGEMENT

Item 12 Waste Management

☐ We will use Appendix T of VAREG 'Guidance for Well Logging, Tracer, and Field Flood Study'

OR

☐ We will use Decay-In-Storage model waste procedure in Appendix T of VAREG, 'Guidance for Well Logging, Tracer, and Field Flood Study'

AND/OR

☐ We will use Disposal of Liquids Into Sanitary Sewage (**12VAC5-481-930**) model waste procedure in Appendix T of VAREG, 'Guidance for Well Logging, Tracer, and Field Flood Study'

OR

☐ We have attached our procedures for waste collection, storage and disposal by any of the authorized methods and request authorization for the methods described.

SPECIFIC LICENSE FEE

Item 13 License Fees (12VAC5-490).

Category:	Application Fee Enclosed (For new applications):
	☐ Yes ☐ No Amount Enclosed $

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

Item 14.

I hereby certify that this application was prepared in conformance with **12VAC5-481**, '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

VDH Form,
'Certificate of Disposition of Material'

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

CERTIFICATE OF DISPOSITION OF MATERIALS

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

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

CONTACT INFORMATION

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

TERMINATION AND DISPOSITION INFORMATION

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

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

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

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

☐ Transferred to: Name Address

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

Issued by (Licensing Agency):

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

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

☐ Other (Attach additional pages)

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

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

Name:

Address:

Contact Person Telephone Number: ( ) - x

Additional remarks (Attach additional pages if necessary.)

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

Item 10.

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

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

Print Name and Title of Above Signatroy

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 Radioactive Material Program Director:

As [job title] of [name of licensee], I have delegated authority for all matters pertaining to our Virginia 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 D

Reserved

Appendix E

Reserved

Appendix F

Field Flood Studies/Enhanced Recovery of Oil and Gas Wells

Field Flood Studies/Enhanced Recovery of Oil and Gas Wells

A formal contractual agreement with well operator or owner should specify control points at which samples will be taken, establish criteria for setting minimum sample requirements, and confirm the willingness of the client company to abide by effluent restrictions and undertake remedial action, if required. The following is an example: samples of recovered fluids or gas will be collected and measured according to the established
sampling schedule and appropriate remedial action will be taken if accidents or incidents occurred that may result in the release of licensed materials to the environment. For example, if the concentration in the recovered fluid or gas approaches or exceeds the design limits, remedial action should be taken, such as reducing the injection pressure, temporarily shutting in the well, or diluting with non-tracer-bearing gas.

Planning Stage

Reservoir Information
Describe the reservoir information that you need in order to design a radioisotope tracer study for a field flood operation. Examples of reservoir information are shown below:

- Reservoir volume
- Reservoir thickness
- Porosity
- Injected volumes (liquids/gases)
- Oil/water saturation ratios

Project Design
Outline the design of the tracer application requested. Examples of items to consider are the following:

- Choice of radionuclides and method used to determine (1) the amount of radionuclide to be injected, and (2) the expected concentration of radionuclide in the fluids (gas, water, oil) at a recovery well site. Indicate your adherence to the ALARA principle
- How breakthrough time is predicted
- How tracer concentrations in the recovered liquids and gases are estimated
- How the sampling schedule at production wellheads is determined. Include a description of how you would determine when sampling could be discontinued. As an example, monitoring of samples may be ended when the design life of the project is completed, unless the effluent concentration at the control point is above a specified fraction of the maximum permissible concentration (as listed for unrestricted areas in **12VAC5-481, 'Virginia Radiation Protection Regulations', Part IV, 'Standards for Protection Against Radiation'**) and is increasing. In that case, the control point will be monitored until the concentration is below the specified fraction of the annual average concentration specified in **12VAC5-481-3690.**

Pre-injection Stage

Transportation of licensed materials.
State that the applicant will comply with VDH and DOT regulations pertaining to the transportation of licensed material. Particular attention should be directed to monitoring requirements upon receipt of packages containing licensed materials.

Integrity of wellhead assembly and wellbore.
Describe the test procedures used to ensure that the wellhead assembly, including injection equipment, will not leak under operating conditions. Describe the procedures used to ensure that the wellbore will not leak underground. For example, if the injection well operates properly for a 2-week period, integrity of the wellbore may be considered ensured.

Injection Stage

Outline radiation safety practices during injection process. Following are examples of practices:

- Remain upwind, if practical.
- Keep nonessential personnel at a distance.
- Use personnel monitoring devices (TLD, OSL, film badges, finger badges, pocket dosimeters, etc.) and other radiation detection instruments in your monitoring and surveillance programs.
- Use special tools and devices to handle licensed material and to facilitate the injection process.
- Perform visual inspection, check pressure gauge, etc., to assure absence of leaks and proper delivery of injection liquid or gas.
- Continuously or intermittently monitor radiation levels outside the injection assembly to assure that the injection is proceeding according to the plan. Allow sufficient time before opening wellhead assembly.

Post-injection Stage

Outline radiation safety practices that will be put into place after the injection phase is completed. Examples of practices include the following:

- Check exposure rate at wellhead assembly for residual activity.
- Take smear samples to detect removable contamination on wellhead assembly.
- Clean reusable tools and check for residual activity before securing for reuse.
- Collect contaminated materials or contaminated tools and package them into an appropriate waste container.
- Establish schedule for taking samples for bioassay when, for example, handling tritium (H-3) exceeding 3.7 Gbq (0.1 Ci) or gaseous H-3 exceeding 3,700 Gbq (100 Ci), or handling radioiodine exceeding 1.85 Gbq (50 mCi) of Iodine-131 or Iodine-125.
- Provide instructions to well operator's personnel for taking post-injection samples and shipping the samples to your facilities for analysis. Include handling, packaging, and shipping procedures.
- Package waste materials for transportation, prepare appropriate labels and shipping papers, and check for radiation level and removable contamination outside the package.
- Measure concentrations of radionuclides in recovered liquids or gases, according to your established sampling schedule.
- Take corrective measures if the concentrations in the recovered liquids or gas approach or exceed design levels.
- Conduct area and personnel monitoring before leaving injection site.

Emergency Procedures

Outline procedures that you will follow in the event of incidents or accidents that release radioactive materials to the environment. Following are examples of incidents and accidents:

- Discovering a leaking source in a shipping container
- Dropping and breaking a source container, thereby spilling the source on the ground
- Detecting leakage of radioactive materials from wellhead assembly
- Measuring concentrations in liquids or gas from production wells exceeding limits specified in **12VAC5-481-3690**, Table 2 of reference.

Reporting, Record Keeping, and Notification

Outline the report that will be submitted to the agency and the records maintained regarding the field flood injections. Following are examples of releases to include: records on the identification of wells, radionuclides, and quantities injected; concentrations of radionuclides in liquids or gases produced at production wells; and concentrations of radionuclides in products released from the field. Also outline the procedures you will follow in case of accidents; and procedures for notifying the proper persons or organizations, such as your company management (RSO), well operator or owner, and state, federal, or municipal governmental agencies involved with the control and oversight of affected wells.

Waste Management

The applicant should outline the procedures for disposing of licensed material. Wastes from tracer operations such as unused materials, and contaminated wipes, gloves, tools, clothing, containers, etc., should be disposed of in accordance with **12VAC5-481, 'Virginia Radiation Protection Regulations', Part IV, 'Standards for Protection Against Radiation'**. Recovered waste fluids that contain radioactive tracers should either be re-injected or treated as radioactive waste. A commonly used method of disposal is transfer to a commercial firm licensed by VDH, NRC, or another Agreement State to accept radioactive wastes. In dealing with these firms, prior contact is needed to determine the specific services they can provide. If commercial services will be used, this should be specified.

Appendix G

Suggested Well Logging and Field Flood Audit Checklist

Suggested Well Logging and Field Flood Audit Checklist

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

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

Next Audit Date: _____

Auditor Date (Signature): _____ Date: _____

Management Review Date (Signature): _____ Date: _____

Type of Inspection: ( ) Announced ( ) Unannounced

Summary of Findings and Actions

[ ] No violations cited
[ ] Self-identified Violation(s)
[ ] Concerns

A. ORGANIZATION AND SCOPE OF PROGRAM

Organization and scope of radiation safety program in accordance with application and the license.

B. MANAGEMENT OVERSIGHT

1. Radiation Safety Officer

2. Audits, Reviews, or Inspections

12VAC5-481-630	Radiation protection programs.
12VAC5-481-990	Records of radiation protection programs.

Audits required by license conditions.

3. Use by Authorized Individuals.

Management structure and control as specified in the license.

4. ALARA

12VAC5-481-630	Radiation protection program.

C. FACILITIES

1. Facilities as Described.

Facilities as described in the license.

2. Storage

12VAC5-481-840	Security and control of licensed or registered sources of radiation.
12VAC5-481-3180,	Storage precautions.
12VAC5-481-3190,	Transport precautions.
12VAC5-481-3250	Labeling.

D. EQUIPMENT AND INSTRUMENTATION

1. Instruments and Equipment

12VAC5-481-3200 Radiation survey instruments.

Radiation detection instruments and equipment as described in the license.

2. Sources, Source Holders, Tools

12VAC5-481-3180 Storage precautions.
12VAC5-481-3190 Transport precautions.
12VAC5-481-3250 Labeling.

Equipment and instrumentation as specified in the license.

E. MATERIAL USE, CONTROL, AND TRANSFER

1. Security and Control

12VAC5-481-10 Definitions (restricted area and unrestricted area).
12VAC5-481-840 Security and control of licensed or registered sources of radiation.
12VAC5-481-3300 Security.

2. Receipt and Transfer of Licensed Material

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

3. Isotope, Chemical Form, Quantity, and Use

12VAC5-481-3220 Physical inventory.
12VAC5-481-3261 Radioactive markers.

Receipt and transfer as described in the license.

F. INSPECTION AND MAINTENANCE

12VAC5-481-3260 Inspection and maintenance.
10 CFR 21.21 Notification of failure to comply or existence of a defect and its evaluation.

Inspection and maintenance as described in the license.

G. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

1. Area Surveys

12VAC5-481-730 Compliance with dose limits for individual members of the public.
12VAC5-481-750 General.
12VAC5-481-1000 Records of surveys.
12VAC5-481-1050 Records of dose to individual members of the public.
12VAC5-481-3340 Radiation surveys and contamination control.

Area radiation surveys and contamination control as described in the license.

2. Leak Tests and Inventories

12VAC5-481-3210 Leak testing of sealed sources.

Leak test conducted in accordance with applicable license conditions.

3. Tracer Studies

12VAC5-481-3320 Subsurface tracer studies.

12VAC5-481-3240 Design, performance, and certification criteria for sealed sources used in downhole operations

H. TRAINING AND INSTRUCTIONS TO WORKERS

General

12VAC5-481-2270 Instruction to workers.

12VAC5-481-3270 Training requirements.

Knowledge of **12VAC5-481, 'Virginia Radiation Protection Regulations', Part IV, 'Standards for Protection Against Radiation'** radiation protection procedures and requirements.

Training program for personnel in accordance with the license.

I. RADIATION PROTECTION

1. Radiation Protection Program

a. Exposure evaluation

12VAC5-481-750 General.

b. Programs

12VAC5-481-630 Radiation protection programs.

2. Dosimetry

a. Dose Limits

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

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

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

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

b. External

12VAC5-481-3290 Personnel Monitoring.

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

12VAC5-481-750 General.

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

Dosimetry provided in accordance with the license.

c. Internal

12VAC5-481-3290 Personnel Monitoring

12VAC5-481-670 Determination of internal exposure.

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

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

12VAC5-481-820 Use of other controls.

12VAC5-481-830 Use of respiratory protection equipment.

3. Records

12VAC5-481-990	Records of radiation protection programs.
12VAC5-481-1000	Records of surveys.
12VAC5-481-680	Determination of prior occupational dose.
12VAC5-481-1040	Records of individual monitoring results.

J. RADIOACTIVE WASTE MANAGEMENT

1. Disposal

12VAC5-481-570	Transfer of byproduct material.
12VAC5-481-880	Labeling containers and radiation machines.
12VAC5-481-910	General requirements.
12VAC5-481-1000	Records of surveys.
12VAC5-481-1060	Records of waste disposal.
12VAC5-481-930	Disposal by release into sanitary sewerage.

2. Effluents

a. General

Maintaining effluents from facilities/job sites As Low as Is Reasonably Achievable (ALARA).

b. Release to septic tanks

12VAC5-481-10	Definitions (sanitary sewerage).
12VAC5-481-3690	Annual Limits on Intake (ALI) and Derived Air Concentrations (DACs) of radionuclides for occupational exposure; effluent concentrations; concentrations.

c. Incineration of waste

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

d. Control of air effluents and ashes

12VAC5-481-640	Occupational dose limits for adults.
12VAC5-481-720	Dose limits for individual members of the public.
12VAC5-481-750	General.
12VAC5-481-810	Use of process or other engineering controls.

Incineration conducted in accordance with license condition.

3. Waste Management

a. General

12VAC5-481-910	General requirements.

Radioactive Waste Management - Inspection of Waste Generator Requirements of **12VAC5-481, 'Virginia Radiation Protection Regulations', Part IV and Part XI.**

b. Waste compacted

Applicable license conditions.

c. Waste storage areas

12VAC5-481-840	Security and control of licensed or registered sources of radiation.
12VAC5-481-860	Posting requirements.
12VAC5-481-880	Labeling containers and radiation machines.

Waste storage areas in accordance with the license.

d. Packaging, Control, and Tracking

12VAC5-481-3710	Requirements for transfers of low-level radioactive waste intended for disposal at land disposal facilities and manifests.
12VAC5-481-960	Transfer for Disposal and Manifests.
12VAC5-481-2571	Waste classification.
12VAC5-481-2572	Waste characteristics.

e. Transfer

12VAC5-481-3710	Requirements for transfers of low-level radioactive waste intended for disposal at land disposal facilities and manifests.
12VAC5-481-910	General requirements.
12VAC5-481-960	Transfer for disposal and manifests.

f. Records

12VAC5-481-1000	Records of surveys.
12VAC5-481-1060	Records of waste disposal.

K. DECOMMISSIONING

12VAC5-481-510	Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.
12VAC5-481-1161	Radiological criteria for license termination.

L. TRANSPORTATION

1. General

Hazard Communication for Class 7 (Radioactive) Materials.

12VAC5-481-2980	Transportation of licensed material.

Implementation of Revised **49 CFR Parts 100-179** and **12VAC5-481, 'Virginia Radiation Protection Regulations', Part XIII.**

2. Shippers - Requirements for Shipments and Packaging

a. General Requirements

49 CFR Part 173, Subpart I	Class 7 (radioactive) materials.
49 CFR 173.24	General requirements for packaging and packages.
49 CFR 173.448	General transportation requirements.
49 CFR 173.435	Table of A_1 and A_2 values for radionuclides.

b. Transport Quantities

12VAC5-481-10	Definitions.

i. All quantities

12VAC5-481-10	Definitions.
49 CFR 173.410	General design requirements.
49 CFR 173.441	Radiation level limitations.
49 CFR 173.443	Contamination control.
49 CFR 173.475	Quality control requirements prior to each shipment of of Class 7 (radioactive) materials.
49 CFR 173.476	Approval of special form Class 7 (radioactive) materials. ii. Limited quantities
49 CFR 173.421	Excepted packages for limited quantities of Class 7 (radioactive) materials.

49 CFR 173.422	Additional requirements for excepted packages containing Class 7 (radioactive) materials. iii. Type A quantities
49 CFR 173.412	Additional design requirements for Type A packages.
49 CFR 173.415	Authorized Type A packages.
49 CFR 178.350	Specification 7A; general packaging, Type A. iv. Type B quantities v. LSA material and SCO
49 CFR 173.403	Definitions.
49 CFR 173.427	Transport requirements for low specific activity (LSA) Class 7 (radioactive) materials and surface contaminated objects (SCO).

c. HAZMAT Communication Requirements

49 CFR 172.200-205	Shipping papers.
49 CFR 172.300-338	Marking.
49 CFR 172.400-450	Labeling.
49 CFR 172.500-560	Placarding.
49 CFR 172.600-604	Emergency response information.

3. HAZMAT Training

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

4. Transportation by Public Highway

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

M. NOTIFICATIONS AND REPORTS

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

N. POSTING AND LABELING

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

O. FIELD STATIONS AND TEMPORARY JOB SITES

1. Documents and Records at Field Stations

12VAC5-481-3350 Documents and records required at field stations.
Records at field stations as required by license conditions.

2. **12VAC5-481-3360** Documents and records required at temporary job sites.
Records at temporary job sites as required by license conditions.

P. ABANDONMENT OF SOURCES

12VAC5-481-3160	Agreement with well owner or operator.
12VAC5-481-3370	Notification of incidents, abandonment, and lost sources.

Q. INDEPENDENT AND CONFIRMATORY MEASUREMENTS

R. PERSONNEL CONTACTED

Name, Title, Date of Contact

Appendix H

Information Needed for Transfer of Control Application

Information Needed for Transfer of Control Application

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

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

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

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

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

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

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

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

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

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

Appendix I

Guidance on Decommissioning Funding Plan and Financial Assurance

Guidance on Decommissioning Funding Plan and Financial Assurance

Determining Need for a Decommissioning Funding Plan and Financial Assurance

Table 8 and the worksheet in **Table 9** are used to determine the need for certification of financial assurance (F/A) for decommissioning or a decommissioning funding plan (DFP), as required by **12VAC5-481-450 C. Table 8** is a listing of isotopes with a half-life of greater than or equal to 120 days used in well logging and tracer operations. If the applicant proposes to use isotopes with a half-life greater than or equal to 120 days, divide the requested possession limit (in millicuries for unsealed material and curies for sealed sources) of the isotope by the value for that isotope in **Table 8**. 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 **Table 9**. Add the fractions in the column and place the total in the row labeled total (i.e., 'sum of the ratios').

Table 8. Isotopes With Half-lives Greater Than or Equal to 120 Days

Isotope	Quantity in Millicuries Requiring $225,000 Financial Assurance	Quantity in Millicuries Requiring $1,125,000 Financial Assurance	Quantity in Curies Requiring That a Decommissioning Funding Plan Be Submitted
Unsealed Licensed Material			
Calcium-45	10	100	1000
Carbon-14	100	1000	10000
Hydrogen-3	1000	10000	100000
Krypton-85	100	1000	10000
Nickel-63	10	100	1000
Silver-110m	1	10	100
Any alpha-emitting radionuclide not listed above with a half-life greater then or equal to 120 days.			
Sealed Sources			
Isotope			**Quantity in Curies Requiring $113,000 of Financial Assurance**
Americium-241			100
Cesium-137			100000
Cobalt-60			10000
Hydrogen-3			10000000

Note: 1 Curie = 37 gigabecquerels

Table 9. Sample Worksheet for Determining Need for a Decommissioning Funding Plan or Financial Assurance

Isotope	Unsealed Material Activity (Millicuries) ÷ Unsealed Value from Table 8	Sealed Material Activity (Curies) ÷ Sealed Value from Table 8
Total		
Funds required		
	If < 1.0, enter $0 If > 1.0 but < 10.0, enter first level of financial assurance specified in **12VAC5-481-450 C 5** If > 10.0, but < 100.0, enter second level of financial assurance specified in **12VAC5-481-450 C 5** If > 100.0, enter "DFP only"	If < 1.0, enter $0 If > 1.0, enter sealed source financial assurance specified in **12VAC5-481-450 C 5**

If the sum of the fractions is less than 1 for each category (unsealed and sealed), the applicant does not need to submit certification of F/A or a DFP. If the sum of the fractions is greater than 1 for either category (sealed or unsealed), but less than 100, the applicant will need to submit certification of F/A (in the level I or in the level II amount specified in **12VAC5-481-450 C 5**) or a DFP. If the sum of the fractions is greater than 100 for unsealed material, the applicant must submit a DFP.

Reference: "*Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning*" can be found in **10 CFR 30**, Appendix A. "*Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning*" can be found in **10 CFR 30**, Appendix C. 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 J

NRC Letter Dated August 10, 1989, Transmitting Temporary Generic Exemptions to Well Logging Licensees

NRC Letter Dated August 10, 1989, Transmitting Temporary Generic Exemptions to Well Logging Licensees

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

AUG 10 1989

TO: Well Logging Licensees

FROM: John E. Glenn, Chief Medical, Academic, and Commercial Use Safety Branch
Division of Industrial and Medical Nuclear Safety, NMSS

SUBJECT: **10 CFR PART 39.41(A)(3)** TEMPORARY GENERIC EXEMPTION

Attached (Enclosure 1) is a notice of generic exemption that exempts Nuclear Regulatory Commission (NRC) well logging licensees from the requirement to use only sealed sources that meet the prototype testing requirements specified in paragraph 39.41(a)(3) of 10 CFR Part 39 in well logging operations. The exemption applies only to sealed sources that meet certain alternate prototype testing criteria.

Section 39.41 of 10 CFR Part 39 prohibits licensees from using, after July 14, 1989, a sealed source in well logging unless the source is doubly encapsulated; contains licensed material whose chemical and physical forms are as insoluble and non-dispersible as practical; and is prototype performance tested and found to maintain its integrity after each of the following tests: temperature, impact, vibration, puncture, and pressure. These prototype performance tests are the same as the tests specified for well logging sources in American National Standard Institute (ANSI) N542-1977, "*Sealed Radioactive Sources, Classification*", published by the National Bureau of Standards (NBS Handbook 126) in 1978. The notice also provides that NRC intends, through rulemaking, to reevaluate the requirements in Section 39.41(a)(3) for prototype testing of sealed sources. The generic exemption will allow continued use of sealed sources that were prototype tested in accordance with an earlier national standard [United States of America Standards Institute (USASI) N5.10-1968] while NRC reevaluates these requirements.

Also attached are three enclosures that list various sealed source models common to well logging and identifies their suitability for continued use in well logging operations. Enclosure 2 lists those source models which appear to meet Section 39.41 requirements and are approved for continued use. Enclosure 3 identifies those source models whose continued use is authorized under the temporary generic exemption. Enclosure 4 lists those source models that do not meet the requirements of Section 39.41 or the generic exemption and whose use in well logging must be discontinued upon receipt of this letter. When a sealed source is contained (and normally stored) within a device (logging tool), the sealed source manufacturer and model number is shown below the entry. When NRC has been able to determine that a sealed source model was manufactured/ distributed by another company, or more than one model designation may have been used, this information is shown in parentheses below the entry. Neutron generators are shown by the designation "Nu GEN." An asterisk(*) indicates that the source is used within the logging tool's electronics package.

These lists may not be all inclusive; therefore, if you are authorized to use a sealed source model that is not identified on one of the lists, you should contact the individual noted below so that NRC can determine the status of the source. Upon receipt of this letter, the use of any source not listed on either Enclosure 2 or 3 must be discontinued until its suitability for continued use is determined.

Because many manufacturers are located in Agreement States, NRC relied on information from its Sealed Source and Device Registry to determine a source model suitability for continued use. The Registry only summarizes the more detailed information the manufacture/distributor provides to NRC or an Agreement State when registering its sources. If you have information that shows that a source model listed on Enclosure 4 meets the requirements of Section 39.41 or the generic exemption, you may provide this information to NRC and request that the source's status be reconsidered. Alternatively, NRC will reconsider a source's status if such sources are tested and certified by a qualified testing organization as meeting Section 34.91, 10 CFR Part 39 criteria.

If you have any questions about Section 39.41, 10 CFR Part 39 regulatory requirements, the generic exemption, or the suitability of a sealed source for continued use in well logging, you should contact Bruce Carrico at (301)492-0634.

John E. Glenn, Chief
Medical, Academic, and Commercial Use
Safety Branch
Division of Industrial and Medical Nuclear
Safety, NMSS

Enclosures: As stated

WELL LOGGING SEALED SOURCES APPROVED UNDER PART 39 REQUIREMENTS

MANUFACTURER	MODEL
AMERSHAM CORPORATION	AMN.CYn (n = 1 to 14)
AMERSHAM CORPORATION	AMN.CY1
AMERSHAM CORPORATION	AMN.PEn (n = 1 to 4)
AMERSHAM CORPORATION	CDC.CYn (n = 2 to 12)
AMERSHAM CORPORATION	CKC.CDn (n = 2 to 12)
AMERSHAM CORPORATION	CKC.800 SERIES
AMERSHAM CORPORATION	CVN.CDn (n = 2 to 12)
AMERSHAM CORPORATION (GAMMA INDUSTRIES, GENERAL NUCLEAR)	VD (HP)
ANADRILL, INC* ISOTOPE PRODUCTS MODEL 174 SEALED SOURCE	SGS-AA, SGS-BA, OR SGS-CA
COMPROBE, INC. GAMMA INDUSTRIES MODEL VD-HP SEALED SOURCE GULF NUCLEAR, INC. MODEL VL-1 SEALED SOURCE	1203 DENSITY PROBE
DRESSER INDUSTRIES INC. (Nu GEN)	C-58301, C-1O7298
E.I.DUPONT DE NUMOURS & CO. (NEW ENGLAND NUCLEAR)	NER-571
GEARHART INDUSTRIES, INC. (Nu GEN)	013-1004-000
GENERAL ELECTRIC. CO.	GE(N)-Cf-100 SERIES
GULF NUCLEAR, INC. (NEEI)	VL-1
GULF NUCLEAR, INC. (NEEI)	71-1 (NEEI-AMBE-71-1)
KAMAN SCIENCES CORPORATION (Nu GEN)	A-3061
KAMAN SCIENCES CORPORATION (Nu GEN)	A-320
KAMAN SCIENCES CORPORATION (Nu GEN)	A-520

KAMAN SCIENCES CORPORATION (Nu GEN)	E-3010 AND E-3020
MONSANTO CO., DAYTON LABORATORY	H-245258 (NSR-M)
MONSANTO CO., DAYTON LABORATORY	24113
MONSANTO CO., DAYTON LABORATORY	24154-C
MONSANTO CO., DAYTON LABORATORY	24174
MONSANTO CO., DAYTON LABORATORY	24181
MONSANTO CO., DAYTON LABORATORY	24183
P.A. INCORPORATED (MONSANTO)	H-245258 (NSR-M)
P.A. INCORPORATED*	P-194693
UNC NUCLEAR INDUSTRIES	PA2A, PA2B, PT2A, PT2B, PS2A, PS2B (OLD: SM-100)
E.I. DUPONT DE NUMOURS & CO. (NEN) MODEL 478C SEALED SOURCE	
US DEPARTMENT OF ENERGY	SR-CF-100 SERIES

WELL LOGGING SEALED SOURCES APPROVED UNDER THE GENERIC EXEMPTION

MANUFACTURER	MODEL
COMPROBE, INC. GULF NUCLEAR, INC. MODEL CSV SEALED SOURCE	1203 DENSITY PROBE
COMPROBE, INC. GAMMA INDUSTRIES (GAMMATRON) MODEL AN-HP SEALED SOURCE	2103 DENSITY PROBE
E.I.DUPONT DE NUMOURS & CO. (NEW ENGLAND NUCLEAR)	NER-572, NER-582
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	CS-1000 (HP)
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	GNI-NB (HP)
GAMMA INDUSTRIES	NB (HP)
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	NHP-A-#
GAMMA INDUSTRIES	WLG-1
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	AN-HP
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	AN-HPG, RN-HP
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	DA-20
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	DA-5
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	GT-GHP
GULF NUCLEAR, INC. (NEEI)	AMBE-71-2A
GULF NUCLEAR, INC. (NEEI)	0-73-2
GULF NUCLEAR, INC. (NEEI)	CS-2

GULF NUCLEAR, INC. (NEEI)	CSV
MONSANTO CO., DAYTON LABORATORY	24112
MONSANTO CO., DAYTON LABORATORY	24120
PARKWELL LABORATORIES, INC.	PL-104

KNOWN SEALED SOURCES NOT APPROVED FOR USE IN WELL LOGGING

MANUFACTURER	MODEL
AMERSHAM CORPORATION	CD CQ 5987
AMERSHAM CORPORATION	CDC.800 SERIES (.801 TO .811)
DRESSER ATLAS	B89596, B89587, B89598
FRONTIER TECHNOLOGY CORP.	100
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	GNI-DL-4
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	GNI-NB-S-5. 0
GAMMA INDUSTRIES	NB-S-S, NB-S-20
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	PL-AMBE-2.7
GAMMA INDUSTRIES	RC-1 (HP)
GAMMA INDUSTRIES	S-14
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	GT-G
GENERAL NUCLEAR, INC.	GNI-C(G)M-5
GULF NUCLEAR, INC. (NEEI)	CO-50
GULF NUCLEAR, INC. (NEEI)	CS-50

GULF NUCLEAR, INC. (NEEI)	TG-1
GULF NUCLEAR, INC. (NEEI)	72-CO-200
HASTINGS RADIOCHEMICAL WORKS	CS-III-A-100
ICN PHARMACEUTICAL, INC. (US NUCLEAR)	373
ICN PHARMACEUTICAL, INC. (US NUCLEAR)	374
ICN PHARMACEUTICAL, INC. (US NUCLEAR)	376
ICN PHARMACEUTICAL, INC. (US NUCLEAR)	3146
ISOTOPES SPECIALTIES	0-0037
LFE CORPORATION (TRACERLAB)	CS-15
MINNESOTA MINING AND MANUFACTURING	4F6B
MINNESOTA MINING AND MANUFACTURING (REDESIGN OF MODEL 4F68)	4F6H
MINNESOTA MINING AND MANUFACTURING	4F6S
MINNESOTA MINING AND MANUFACTURING	4P6F
MINNESOTA MINING AND MANUFACTURING	4P6U
MINNESOTA MINING AND MANUFACTURING	4P6W
MONSANTO CO., DAYTON LABORATORY (SCHLUMBERGER WELL SERVICES)	H-142525
MONSANTO CO., DAYTON LABORATORY (SCHLUMBERGER WELL SERVICES)	H-207947
MONSANTO CO., DAYTON LABORATORY	MRC
MONSANTO CO., DAYTON LABORATORY	MRC-N-SS-W-AMBE(R)
MONSANTO CO., DAYTON LABORATORY	NS-WELEX

MONSANTO CO., DAYTON LABORATORY	2410
MONSANTO CO., DAYTON LABORATORY	24154-B
NUCLEAR MATERIALS AND EQUIPMENT CORP.	NUMEC-AM-62, 63, 100, 123, 154
NUCLEAR MATERIALS AND EQUIPMENT CORP.	NUNEC DWG. 11-B-208
PARKWELL LABORATORIES, INC.	PL-AMBE
SCHLUMBERGER	DWG H-1061850
SCHLUMBERGER (MONSANTO, NUMEC)	DWG H-115686
SCHLUMBERGER	DWG H-123515
SCHLUMBERGER	DWG H-123837
SCHLUMBERGER	DWG H-142108
SCHLUMBERGER	DWG H-218733
SCHLUMBERGER	DWG H-239681
SCHLUMBERGER	DWG X-113176
SCHLUMBERGER WELL SERVICES	NSR-R
SCHLUMBERGER WELL SERVICES*	P-194693
WELL RECONNAISANCE, INC.	10411
WSI	A4794

Appendix K

Typical Duties and Responsibilities of the Radiation Safety Officer

Typical Duties and Responsibilities of the Radiation Safety Officer

The RSO's duties and responsibilities include ensuring radiological safety and compliance with VDH and DOT regulations and the conditions of the license (see **Table 2**). Typically, these duties and responsibilities include ensuring the following:

- Secure from management the authorization to stop activities involving licensed material considered unsafe by the RSO.
- Maintain radiation exposures ALARA.
- Develop, distribute, implement, and maintain up-to-date operating and emergency procedures.
- Ensure that the possession, installation, relocation, use, storage, repair, and maintenance of licensed material and well logging equipment are consistent with the limitations in the license, the Sealed Source and Device Registration Certificate(s), and manufacturer's recommendations and instructions.
- Ensure that evaluations are performed to demonstrate that individuals who are not provided personnel monitoring devices will be unlikely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided.
- Ensure that personnel monitoring devices for well logging supervisors and assistants are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained.
- Determine that licensed materials are maintained secure when not under the constant surveillance of logging personnel.
- Maintain documentation to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from licensed operations does not exceed the annual limit for members of the public.
- Ensure that proper authorities are notified of incidents such as fire, theft, or damage to sealed sources, loss of well logging sources downhole, and non-routine levels of radioactive contamination at well logging, tracer, and field study operations.
- Ensure that unusual occurrences are investigated, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken.
- Perform and document radiation safety program audits annually.
- Identify violations of regulations, license conditions, or program weaknesses, and develop, implement, and document corrective actions.
- Ensure that licensed material is transported in accordance with all applicable VDH and DOT requirements.
- Ensure that licensed material is disposed of properly.
- Keep license up-to-date by amending and renewing, as required. Ensure that renewals are made in a timely manner.
- Serve as the licensee's liaison officer with the agency on license or inspection matters.
- Control procurement and disposal of licensed material, maintain associated records, and ensure that licensed materials that are possessed or used by the applicant are limited to those specified in the license.
- Establish and conduct the training program for logging supervisors and logging assistants.
- Examine and determine the competence of logging personnel.

- Ensure that the licensed materials are used only by those individuals who have satisfactorily completed appropriate training programs or who are authorized by the license.
- Establish and maintain a personnel monitoring program and ensure that all users wear personnel monitoring equipment, such as film badges, OSL, or TLD.
- Establish and maintain storage facilities.
- Establish and maintain the leak test program and supervise leak testing of sealed sources.
- Procure and maintain radiation survey instruments.
- Establish and maintain a survey instrument calibration program.
- Develop and maintain up-to-date operating and emergency procedures.
- Conduct physical inventories and maintain utilization logs.
- Review and ensure maintenance of those records kept by others.
- Conduct radiation safety inspections of licensed activities periodically to ensure compliance with the regulations and license conditions.
- Serve as a point of contact and give assistance in case of emergency (well logging tool damage, theft,
  fire, etc.) to ensure that the proper authorities are notified.
- Investigate the cause of incidents and determine necessary preventative action.
- Act in an advisory capacity to the licensee's management and logging personnel.
- Establish a procedure for evaluating and reporting equipment defects and noncompliance pursuant to **10 CFR Part 21**.

Appendix L

Well Logging Supervisor and Logging Assistant Training Requirements

Well Logging Supervisor and Logging Assistant Training Requirements

Requirement		Training Criteria
12VAC5-481-3270 A		Logging Supervisor
A.	Receive Training in **12VAC5-481-3270 A** Topics (Classroom Training – Approximately 24 hours in length)	Topics in **12VAC5-481-3270 A** **Fundamentals of Radiation Safety** • Characteristics of gamma radiation • Units of radiation dose and quantity of radioactivity • Hazards of exposure to radiation • Levels of radiation from licensed material • Methods of controlling radiation dose (time, distance, shielding) • Radiation safety practices, including prevention of contamination, and methods of decontamination **Radiation Detection Instruments** • Use, operation, calibration, and limitations • Survey techniques • Use of personnel monitoring equipment **Equipment to be Used** • Operation of equipment, including source handling equipment and remote handling tools • Storage, control, and disposal of licensed material • Inspection and maintenance of equipment **Requirements of Pertinent State and Federal Regulations** **Case histories of accidents in well logging operations**

Table 10. 12VAC5-481, Part XIV Training Requirements

Requirement 12VAC5-481-3270 A		Training Criteria Logging Supervisor
B.	On-the-Job Training – using sealed sources 160 hours for mineral logging licensee, or a licensee using sealed sources with activities less than 500 millicuries **OR** 3 months or 520 hours for gas or oil well logging operations using sealed sources with activities greater then 500 millicuries	Under the supervision of a qualified logging supervisor
C.	On-the-Job Training – using tracer materials **Single Well Tracer Operations** 3 months or 520 hours or completion of 50 tracer operations **Field Flood Operations** 3 months or 520 hours or completion of 3 field flood tracer operations involving multiple wells	Under the supervision of a qualified logging supervisor
D.	Completion of a Written Examination	Complete a written examination submitted and approved by VDH
E.	Must receive Copies of and Instruction in: (Classroom Training – Approximately 8 hours in length)	VDH Regulations • Applicable sections of **12VAC5-481, Part IV, X, and XIV.** • The VDH license under which the logging supervisor will perform well logging • The operating and emergency procedures required by **12VAC5-481-3280**
F.	Receive Equipment Training (Approximately 4 hours in length)	Training includes: • Well Logging Equipment • Sealed Sources • Handling Equipment • Survey meters • Daily inspection
G.	Demonstrate Understanding in Use of Well Logging Equipment by Passing Practical Field Exam	Questions on topics determined by the licensee Use the Well Logging Supervisor/Logging Assistant Inspection Checklist as a potential source of questions

Table 10. 12VAC5-481, Part XIV Training Requirements

	Requirement 12VAC5-481-3270 A	Training Criteria Logging Supervisor
I.	Annual Refresher Training	Review the following: • Annual radiation safety program review • New procedures, equipment, or techniques • New regulations • Observations and deficiencies during audits of well logging supervisor and logging assistants and discussion of any significant incidents or accidents involving well logging • Employee questions
J.	Records	To be maintained in accordance with **12VAC5-481-3270 D**

	Requirement 12VAC5-481-3270 B	Training Criteria Logging Assistant
A.	Must receive Copies of and Instruction in: (Classroom Training – Approximately 8 hours in length)	VDH Regulations • Applicable sections of **12VAC5-481, Part IV, X, and XIV** • Operating and emergency procedures required by **12VAC5-481-3280**
B.	Pass Oral or Written Exam	Complete a written examination submitted and approved by VDH
C.	Receive Equipment Training (Approximately 2-4 hours in length)	Training under the supervision of a qualified well logging supervisor appropriate for the logging assistant's intended job responsibilities: • Well logging equipment • Sealed sources • Handling equipment • Survey meters • Daily inspection
D.	Annual Refresher Training	Review the following: • Any significant item identified in the annual review of the radiation safety program • New procedures or equipment • New regulations • Observations and deficiencies during audits and discussion of any significant incidents or accidents involving well logging operations • Employee questions
E.	Records	To be maintained in accordance with **12VAC5-481-3270 D**

Table 10. 12VAC5-481, Part XIV Training Requirements

Appendix M

Annual Internal Job Performance Inspection Checklist for Well Logging Supervisors and Well Logging Assistants

Annual Internal Job Performance Inspection Checklist for Well Logging Supervisors and Well Logging Assistants

Well Logging Location _____

Date _____ **Time** _____

Logging Supervisor _____

Logging Assistant _____

Inspector _____

Yes No Questions

1. Film, TLD, or OSL badge available and properly worn?

2. Individuals working within the restricted area wearing TLD, OSL, or film badges or dosimeters?

3. Restricted areas properly controlled to prevent unauthorized entry?

4. Calibrated and properly operating survey meter and evidence of its latest calibration available?

5. Latest survey records as required by **12VAC5-481-3350** or **12VAC5-481-3360** available?

6. Measurements taken of positions occupied in transport vehicle?

7. Measurement taken of vehicle exterior?

8. Contamination check performed of well logging tool prior to transport?

9. Measurements taken before and after subsurface tracer use?

10. Shipping papers for transportation of radioactive material available and properly filled out?

11. Utilization log properly filled out?

12. Defective well logging equipment being used?

13. Copy of the applicant's operating and emergency procedures available at the site?

14. Radioactive isotopes stored and secured properly to prevent unauthorized removal?

15. Storage area properly posted with "*Caution...*" or "*Danger Radioactive Material*" signs?

16. Additional items of noncompliance noted during this audit? (If any, explain, in remarks.)

Remarks:

Appendix N

Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

Radiation Monitoring Instrument Specifications

The specifications in **Table 11** will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their 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	Carbon-14 or higher (dependent on window thickness)	Moderate

Stationary Instruments Used to Measure Wipe, Bioassay, and Samples from Tracer/Field Flood Study Job Sites

Detectors	Radiation	Energy Range	Efficiency
Liquid Scintillation Counter*	Alpha	All energies	High
	Beta	All energies	High
	Gamma		Moderate
Gamma Spectroscopy System using a (NaI)* detector	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

Table 11 Typical Survey.

Note: Table adapted from The Health Physics & Radiological Health Handbook, Revised Edition, Edited by Bernard Shleien, 1992 (except for * items).

Model Instrument Calibration Program

Training

Before allowing an individual to perform survey instrument calibrations, the RSO will ensure that he or she has sufficient training and experience to perform independent survey instrument calibrations. Classroom training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:

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

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

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

Facilities and Equipment 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

Model 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 to be within ± 5% accuracy 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 or develop energy curves to compensate for differing energies
- For dose rate and exposure rate instruments, the source should be strong enough to give an exposure rate of at least about 7.7×10^{-6} coulombs/kilogram/hour (30 mR/hr) at 100 cm [e.g., 3.1 gigabecquerels (85 mCi) of cesium-137 or 7.8×10^{2} megabecquerels (21 mCi) of cobalt-60]

The three kinds of scales frequently used on dose or dose rate survey meters are calibrated as follows[3]:

- Linear readout instruments with a single calibration control for all scales should 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 should be adjusted on each scale. After adjustment, the response of the instrument should be checked at approximately 20% and 80% of full scale. The instrument's readings should be within ±15% of the conventionally true values for the lower point and ±10% for the upper point.
- Logarithmic readout instruments, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. The instrument should be

adjusted for each scale according to site specifications or the manufacturer's specifications. After adjustment, calibration should be checked at a minimum of one point on each decade. Instrument readings should have a maximum deviation from the conventionally true value of no more than 10% of the full decade value.

- Meters with a digital display device shall be calibrated the same as meters with a linear scale
- Readings above 2.58 x 10^{-4} coulomb/kilogram/hour (1 R/hr) need not be calibrated, but such scales should be checked for operation and response to radiation
- The inverse square and radioactive decay laws should be used to correct changes in exposure rate due to changes in distance or source decay.

Surface Contamination Measurement Instruments

- A survey meter's efficiency must be determined by using sealed sources with similar energies and types of radiation that the survey instrument will be used to measure or by developing energy curves to compensate for differing energies.
- If each scale has a calibration potentiometer, the reading should be adjusted to read the conventionally true value at approximately 80% of full scale, and the reading at approximately 20% of full scale should be observed. If only one calibration potentiometer is available, the reading should be adjusted at mid-scale on one of the scales, and readings on the other scales should be observed. Readings should be within 20% of the conventionally true value.

Model 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 to be within ± 5% accuracy by NIST.
- Approximate the same energy and type of radiation as the samples that the calibrated device will be used to measure.

Calibration

- Calibration of survey instruments used in well logging procedures for assessing dose or exposure rates must be conducted at least every 6 months or after instrument servicing
- Calibration must produce readings within ±20% of the actual values over the range of the instrument
- Calibration of liquid scintillation counters will include quench correction.

Calibration Records

Calibration reports, for all survey instruments, should indicate the procedure used and the data obtained. The calibration record should include:

- The owner or user of the instrument
- A description of the instrument, including the manufacturer's name, model number, serial number, and type of detector
- A description of the calibration source, including the exposure rate at a specified distance or activity on a specified date
- For each calibration point, the calculated exposure rate or count rate, the indicated exposure rate or count rate, the deduced correction factor (the calculated exposure rate or count rate divided by the indicated exposure rate or count rate), and the scale selected on the instrument

- For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)
- For instruments with internal detectors, the angle between radiation flux field and a specified surface of the instrument
- For detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure
- The exposure rate or count rate from a check source, if used
- The name of the person who performed the calibration and the date it was performed.

The following information 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
- The apparent exposure rate or count rate from the check source, if used.

References:

1. Draft Regulatory Guide FC 413-4, "*Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments*", dated June 1985.
2. "*The Health Physics & Radiological Health Handbook, Revised Edition*", edited by Bernard Shleien, dated 1992.
3. 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: www.ansi.org.

Appendix O

Guidance for Demonstrating that Unmonitored Individuals are Not Likely to Exceed 10 Percent of the Allowable Limits

Guidance for Demonstrating that Unmonitored Individuals are Not Likely to Exceed 10 Percent of the Allowable Limits

Dosimetry is required for individual adults who are likely to receive in 1 year an occupational dose from sources external to the body in excess of 10% of the applicable regulatory limits in **12VAC5-481-630**. However, logging supervisors or logging assistants are required by **12VAC5-481-3290** to wear either a film badge, optically stimulated luminescent (OSL) badge, or a thermoluminescent dosimeter (TLD) when handling licensed tracer materials or sealed sources. In instances where pocket chambers are used instead of film badges or TLDs to assess radiation dosage of personnel who are not logging supervisors or logging assistants, a check of the response of the dosimeters to radiation should be made every 12 months. Acceptable pocket dosimeters should read within plus or minus 20% of the true radiation dose. To demonstrate to the agency that dosimetry is **not** required for non-logging personnel, a licensee needs to have available an evaluation demonstrating that these non-monitored workers are not likely to exceed 10% of the applicable annual limits — 5 mSv (500 millirems) per year.

The applicable Total Effective Dose Equivalent (whole body) limit is 50 mSv (5 rems) per year, and 10% of that value is 5 mSv (500 millirems) per year.

Three common ways that individuals may exceed 10% of the applicable limits are mishandling tracer radioisotopes, logging tools, or any devices containing sealed sources. However, most routine well logging or tracer activities result in minimal doses to well logging and tracer personnel. A licensee will need to conduct an evaluation of doses to occupationally exposed workers who could, in performing tasks involving the handling of radioactive materials, have a need for dosimetry.

Example: A careful radiation measurement using a survey meter of the location producing the highest dose rate at the rear of the logging truck where radioactive material is stored in its transport compartment and where mechanics routinely work, is found to be 0.015 mSv/hr (1.5 mrem/hr). Mechanics are not expected to spend any more than a total of 3 hours per week at the location near the storage containers where the sealed sources are housed at the rear of the truck. Based on this measured dose rate, the annual dose is expected to be less than 2.34 mSv (234 mrem). Specifically, 3 hr/wk x 1.5 mrem/hr x 52 wk/yr = 234 mrem. Based on the above, if any mechanic works in the area less than 6.4 hours per week, no dosimetry is required.

Note: 6.4 hours is the total amount of hours it would take for an individual to meet the 5 mSv (500 millirems) per year limit.

Appendix P

Guidance for Demonstrating that Individual Members of the Public will not Receive Doses Exceeding the Allowable Limits

Guidance for Demonstrating that Individual Members of the Public will not Receive Doses Exceeding the Allowable Limits

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 mSv (100 mrem) in one calendar year resulting from the licensee's possession and/or use of licensed materials.

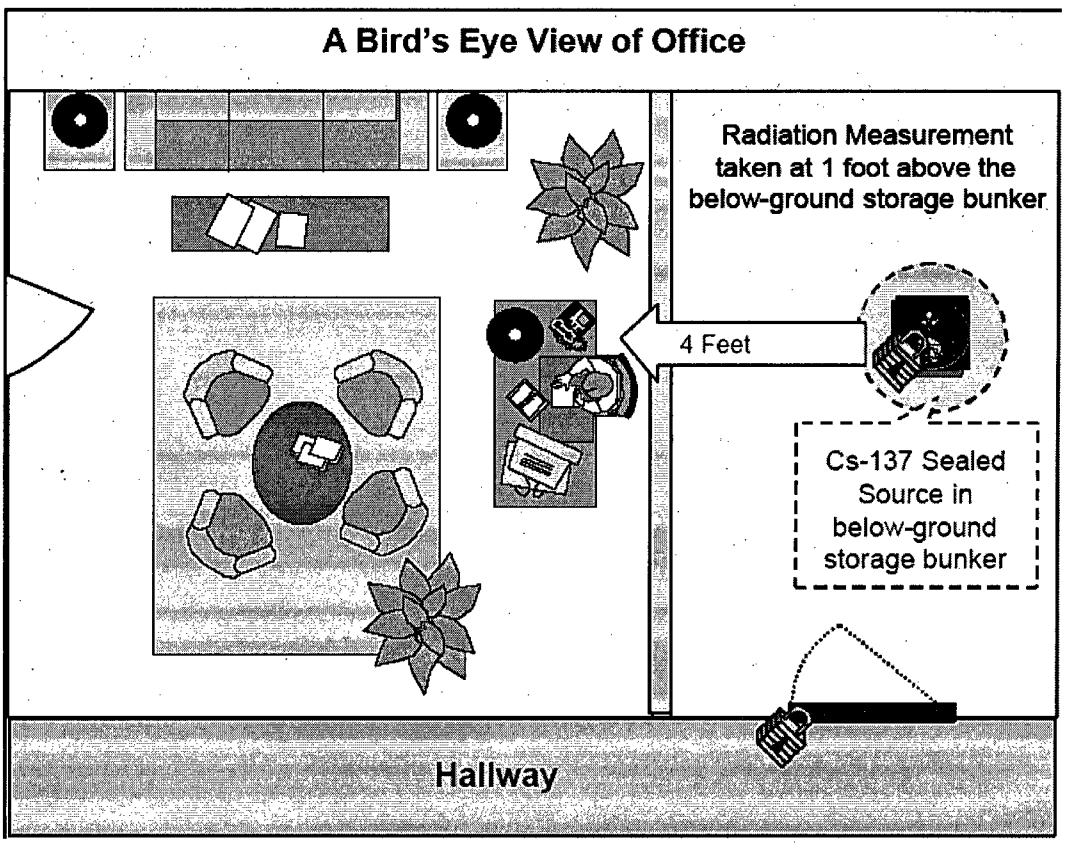
  Members of the public include persons who live, work, or may be near locations where licensed material is used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where it is used or stored.

- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.

  Typical unrestricted areas may include offices, shops, laboratories, areas outside buildings, property, and non-radioactive equipment storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials; however, the licensee may control access to these areas for other reasons, such as security.

Licensees must demonstrate compliance with both of the above regulations. For areas adjacent to facilities where licensed material is used or stored, calculations or a combination of calculations and measurements (e.g., using an environmental TLD) are often used to show compliance.

Figure 4. Bird's Eye View of Office.


A Bird's Eye View of Office
Radiation Measurement taken at 1 foot above the below-ground storage bunker
4 Feet
Cs-137 Sealed Source in below-ground storage bunker
Hallway

Calculation Method

These measurements must be made with calibrated survey meters sufficiently sensitive to measure background levels of radiation. However, licensees must exercise caution when making these measurements, and they must use currently calibrated radiation survey instruments. A maximum dose of 1 mSv (100 mrem) received by an individual over a period of 2080 hours (i.e., a 'work year' of 40 hr/wk for 52 wk/yr) is equal to less than 0.5 microsievert (0.05 mrem) per hour.

This rate is well below the minimum sensitivity of most commonly available GM survey instruments.

Instruments used to make measurements for calculations must be sufficiently sensitive. An instrument equipped with a scintillation-type detector (e.g., NaI(Tl)) or a micro-R meter used in making very low gamma radiation measurements should be adequate.

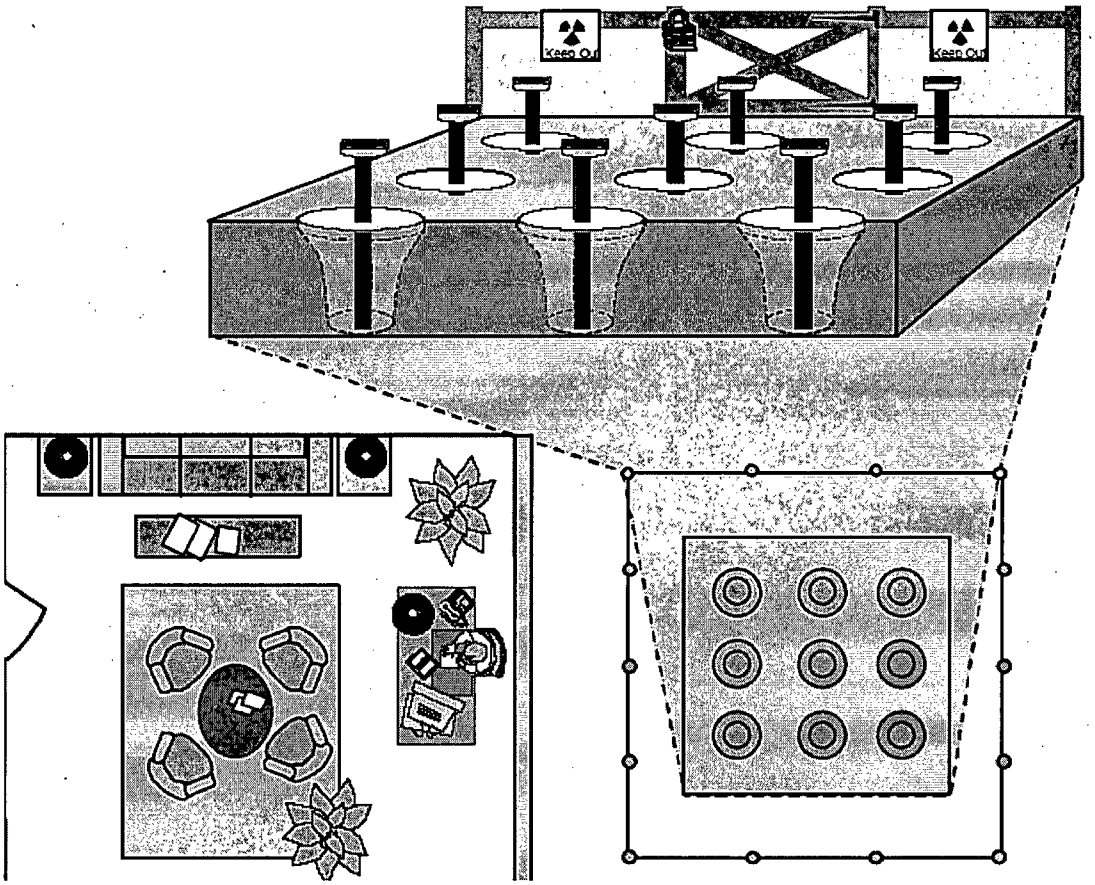
Licensees may also choose to use environmental TLDs in unrestricted areas next to the downhole source storage area for monitoring. This direct measurement method would provide a definitive measurement of actual radiation levels in unrestricted areas without any restrictive assumptions. Records of these measurements can then be evaluated to ensure that rates in unrestricted areas do not exceed the 1 mSv/yr (100 mrem/yr) limit.

TLDs used for personnel monitoring (e.g., LiF) may not have sufficient sensitivity for this purpose. Generally, the minimum reportable dose received is 0.1 mSv (10 mrem). Suppose a TLD monitors dose received and is changed once a month. If the measurements are at the minimum reportable level, the annual dose received could have been about 1.2 mSv (120 mrem), a value in excess of the 1 mSv/yr (100 mrem/yr) limit. If licensees use TLDs to evaluate compliance with the public dose limits, they should consult with their TLD supplier and choose more sensitive TLDs, such as those containing CaF_2 that are used for environmental monitoring.

The combined measurement-calculation method may be used to estimate the maximum dose to a member of the public. The combined measurement-calculation method takes a tiered approach, going through a two-part process, starting with a worst case situation and moving toward more realistic situations. It makes the following simplifications: (1) each Cesium-137 logging source is a point source; (2) typical radiation levels are encountered when the source is in the unshielded position; and (3) no credit is taken for any shielding found between the source storage area and the unrestricted areas. The method is only valid for the source activity at the time of measurement and must be repeated if the source strength or shielding is changed.

Part 1 of the combined measurement-calculation method is simple but conservative. It assumes that an affected member of the public is present 24 hours a day and uses only the inverse square law to determine if the distance between the downhole storage area and the affected member of the public is sufficient to show compliance with the public dose limits. Part 2 considers not only distance, but also the time that the affected member of the public is actually in the area under consideration. Using this approach, licensees make only those calculations that are needed to demonstrate compliance. The results of these calculations typically result in higher radiation levels than would exist at typical facilities, but they provide a method for estimating conservative doses that could be received.

Figure 5. Downhole Storage Array.



Example

To better understand the combined measurement-calculation method, we will examine EZ Well Logging, Inc., a well logging licensee. Yesterday, the company's president noted that the top shield of the downhole storage area is close to an area used by workers whose assigned duties do not include the use of licensed materials, and he asked Joe, the Radiation Safety Officer (RSO), to determine if the company is complying with VDH's regulations.

The area in question is near the floor under the workers' desks, which constitutes the primary shield of the downhole storage area. Joe measures the distance from the shield to the center of the area in question and, using a calibrated survey instrument, measures the highest dose rate at one foot from the shield to be 2 mrem per hour.

Summary of Information

This is the information Joe has or has acquired on the downhole storage area: the dose rate at 1 foot from the top of the shield is 2 mrem/hr and the nearest occupied work area to the face of the shield is 4 ft.

Example: Part 1

Joe's first thought is that the distance between the downhole storage area shield and the area in question may be sufficient to show compliance with the regulation in **12VAC5-481-720**. So, taking a worst case approach, he assumes: 1) the Cesium-137 is constantly located in downhole storage area (i.e., 24 hr/d), and 2) the workers are constantly in the unrestricted work area (i.e., 24 hr/d). Joe proceeds to calculate the dose the workers might receive hourly and yearly from the source, as shown in **Table 12** below.

Step No.	Description	Input Data	Results
1	Multiply the measured dose rate measured at 1.0 ft from the face of the shield floor in mrem/hr by the square of the distance (ft) at which the measurement was made (e. g., 1 foot from the face of the shield)	$2 \times (1)^2$	2
2	Square the distance (ft) from the face of the shield to the nearest unrestricted area, in ft^2	$(4)^2$	16
3	Divide the result of Step 1 by the result of Step 2 to calculate the dose received by an individual in the area near the shield. **HOURLY DOSE RECEIVED FROM SOURCE**, in mrem in an hour	2/16	**0.125**
4	Multiply the result of Step 3 by 40 hr/work week x 52 weeks/year = **MAXIMUM ANNUAL DOSE RECEIVED FROM Cs-137 Source**, in mrem in a year	0.125 x 40 x 52	**260**

Table 12. Calculation Method, Part 1: Hourly and Annual Doses Received from a Logging Source Stored in Above Ground Transportation Container.

Note: The result in Step 3 demonstrates compliance with the 2 mrem in any one hour limit. Re-evaluate if assumptions change. If the result in Step 4 exceeds 100 mrem/yr, proceed to Part 2 of the calculation method.

At this point, Joe is pleased to see that the total dose that an individual could receive in any one hour is only 0.125 mrem in an hour, less than the 2 mrem in any one hour limit but notes that an individual could receive a dose of 260 mrem in a year, higher than the 100 mrem limit.

Example: Part 2

Joe reviews the assumptions and recognizes that the workers are not in area near the shield all of the time. A realistic estimate of the number of hours the workers spend in the area is made, keeping the other assumptions constant (i.e., the source is constantly in the downhole storage area (i.e., 24 hr/d). The annual dose received is then recalculated.

Step No.	Description	Results
7.	A. Average number of hours per day an individual spends in area of concern (e.g., a non-radiation worker spends 1.5 hr/day in area near the shield; the remainder of the day the workers are away from the area assigned to jobs unrelated to radiation)	1.5552
	B. Average number of days per week in area	5
	C. Average number of weeks per year in area (e.g., full time workers)	52
8.	Multiply the results of Step 7.A. by the results of Step 7.B. by the results of Step 7.C. = **AVERAGE NUMBER OF HOURS IN AREA OF CONCERN PER YEAR**	1.5 x 5 x 52 = **390**
9.	Multiply the results in Step **3** by the results of Step 8 = **ANNUAL DOSE RECEIVED FROM CESIUM-137 LOGGING SOURCE CONDSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN**, in mrem in a year	0.125 x 390 = **49**

Table 13. Calculation Method, Part 2: Annual Dose Received from a Logging

Joe is pleased to note that the calculated annual dose received is significantly lower, and does not exceed the 100 mrem in a year limit. Had the result in Step 9 been higher than 100 mrem in a year, then Joe would have not been in compliance and could have done one or more of the following:

- Consider whether the assumptions used to determine occupancy are accurate, revise the assumptions as needed, and recalculate using any new assumptions
- Calculate the effect of any shielding located between the storage area and the floor of the public area — such calculation is beyond the scope of this Appendix
- Take corrective action (e.g., change work patterns to reduce the time spent in the area near the shield) and perform new calculations to demonstrate compliance
- Designate the area inside the use area as a restricted area and the workers as occupationally exposed individuals. This would require controlling access to the area for purposes of radiation protection and training the workers as required by **12VAC5-481-2270**.

Reference: National Council on Radiation Protection and Measurements (NCRP) Report No. 49, "*Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV*", contains helpful information. It is available from NCRP, 7910 Woodmont Avenue, Suite 800, Bethesda, Maryland 20814. NCRP's telephone numbers are: (301) 657-2652 or 1-800-229-2652.

Note that in the example, Joe evaluated the unrestricted area outside only one wall of the downhole storage area. Licensees also need to make similar evaluations for other unrestricted areas and to keep in mind the ALARA principle, taking reasonable steps to keep radiation dose received below regulatory requirements. In addition, licensees need to be alert to changes in situations (e.g., adding sources to the storage area, changing the work habits of the workers, or otherwise changing the estimate of the portion of time spent in the area in question) and to perform additional evaluations, as needed.

RECORD KEEPING: 12VAC5-481-1050 requires licensees to maintain records demonstrating compliance with the dose limits for individual members of the public.

Appendix Q

Notification of Proper Persons in the Event of an Accident

Notification of Proper Persons in the Event of an Accident

Emergency Procedure

Notify the persons listed below of the situation, in the order shown.

Name*	Work Phone Number*	Home Phone Number*
Radiation Safety Officer (RSO)		
Senior Logging Supervisors		
Manufacturers/Distributors		
Consultant		

* Fill in with (and update, as needed) the names and telephone numbers of appropriate personnel (e.g., the Radiation Safety Officer (RSO) or other knowledgeable licensee staff, licensee's consultant, device manufacturer, etc.) to be contacted in case of emergency. Follow the directions provided by the person contacted above.

RSO and Licensee Management

Discuss emergency operating procedures, and ensure no operations are conducted until the situation has been discussed with and approved by the RSO or other knowledgeable staff, consultants, or the device manufacturer. Management should have access to emergency equipment to keep doses as low as reasonably achievable. Emergency equipment may include special survey equipment.

Notify local authorities as well as the agency, as required. (Even if notification is not required, ANY incident may be reported to the agency by calling the emergency number at (804) 864-8150 during business hours or (800) 468-8892, which is staffed 24 hours a day; identify emergency as radiological.) Agency notification is required when sources or devices containing licensed material are lost or stolen and when sealed or unsealed radioactive material or equipment is involved in incidents that may have caused or that threaten to cause an exposure in excess of **12VAC5-481-1100** limits. Reports to the agency must be made within the reporting time frames specified by the regulations. Notification and reporting requirements are found in **12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 10 CFR Part 21.21**, and **12VAC5-481-3370**.

Notifications

Event	Telephone Notification	Written Report	Rule Requirement
Theft or loss of material	Immediate	30 days	**12VAC5-481-1090**
Whole body dose greater then 0.25 Sv (25 rems)	Immediate	30 days	**12VAC5-481-1100**
Extremity dose greater then 2.5 Sv (250 rems)	Immediate	30 days	**12VAC5-481-1100**
Whole body dose greater then 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	**12VAC5-481-1100**
Extremity dose greater then 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	**12VAC5-481-1100**
Whole body dose greater then 0.05 Sv (5 rems)	None	30 days	**12VAC5-481-1110**
Dose to individual member of public greater then 1 mSv (100 rems)	None	30 days	**12VAC5-481-1110**
Defect in equipment that could create a substantial safety hazard	2 days	30 days	**12VAC5-481-1100, 12VAC5-481-1110**
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed VDH limits	Immediate	30 days	**12VAC5-481-1110**
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of VDH limits	24 hours	30 days	**12VAC5-481-1110**
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	**12VAC5-481-1110**
Rupture of sealed source	Immediate	30 days	**12VAC-5-481-3370**
Sealed source becomes lodged in well bore and becomes classified as irretrievable, or licensee is requesting an extension to complete abandonment procedures	24 hours	30 days	**12VAC5-481-3370 B & C**
Leak test of sealed source resulting in leakage greater then 185 Bq (0.005 microcuries)	None	5 days	**12VAC5-481-3210 D**
Failure of any component to perform its intended function	None	30 days	**10 CFR 21.21**

Table 14. VDH Notifications.

Note: Telephone notifications shall be made to the agency at (804) 864-8150 during business hours; (804)674-2400 or (800) 468-8992, which is staffed 24 hours a day. Identify the emergency as radiological.

Appendix R

Model Leak Test Program

Model Leak Test Program

Training

Before allowing an individual to perform leak test analysis independently, the RSO will ensure that the individual has sufficient classroom and on-the-job training to show competency in performing leak test analysis.

Classroom training in the performance of leak test analysis may be provided in the form of lecture, videotape, or self-study. This 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
- Biological effects of radiation.

Appropriate on-the-job training consists of:

- Observing authorized personnel collecting and analyzing leak test samples
- Collecting and analyzing leak test samples under the supervision and in the physical presence of an individual authorized to perform leak tests and leak test analysis

Facilities and Equipment

- To ensure the required sensitivity of measurements, leak tests will be analyzed in a low-background area.
- Before leak test swipes are analyzed, individuals conducting leak tests will use a calibrated and operable survey instrument to check leak test samples for gross contamination. If the sensitivity of the counting system is unknown, the minimum detectable activity (MDA) needs to be determined. The MDA may be determined using the following formula:

$$MDA = \frac{3 + 4.65(BR)^{*}\frac{1}{2}}{Et}$$

where MDA = activity level in disintegrations per minute (dpm)
BR = background rate in counts per minute (cpm)
t = counting time in minutes
E = detector efficiency in counts per disintegration (cpd)

For example:
where BR = 200 cpm
E = 0.1 cpd (10% efficient)
t = 2 minutes

$$MDA = \frac{3 + 4.65(200\ cpm)^{*}\frac{1}{2}}{(0.1\ cpd)(2\ minutes)}$$

A NaI(Tl) well counter system with a single or multi-channel analyzer will be used to count samples from sealed sources containing gamma-emitters (e.g., Cesium-137, Cobalt-60). A liquid scintillation, gas-flow proportional, or solid state counting system will be used to count samples containing alpha-emitters (e.g., Americium-241).

Frequency for Conducting Leak Tests of Sealed Sources

Leak tests on well logging sealed sources will be conducted at intervals not to exceed 6 months, or, for Energy Compensation Sources (ECS) requiring leak tests, at intervals not to exceed 3 years.

Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as the manufacturer's name, model number, serial number, radionuclide, and activity of the sealed source(s).
- 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.
- If available, use a survey meter to monitor exposure.
- Wipe the most accessible area (but not directly from the surface of the source) where contamination would accumulate if the sealed source were leaking, (e.g., the leak test can be taken of the part that connects to the source or the inside of the transport container that has recently transported the source).
- Select an instrument that is sensitive enough to detect 185 Bq (0.005 mCi) of the radionuclide of the sealed source.
- Using the selected instrument, count and record background count rate.
- Check the instrument's counting efficiency using a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within ±5% of the stated value and traceable to primary radiation standard, such as those maintained by the National Institutes of Standards and Technology (NIST).
- 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 Bq (or Ci).

  For example: $\frac{[(\text{cpm from wipe sample}) - (\text{cpm from bkg})]}{\text{efficiency in cpm/Bq}} = \text{Bq on wipe sample}$
- Sign and date the list of sources, data, and calculations. Retain records for 5 years (**12VAC5-481-1000**).

If the wipe test activity is 185 Bq (0.005 microcurie) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly. Also notify the agency.

Appendix S

Transportation - Major DOT Regulations; Sample Shipping Documents, Placards and Labels

Transportation - Major DOT Regulations; Sample Shipping Documents, Placards and Labels

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

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

The following are the major areas in DOT regulations most relevant for transporting licensed material that is shipped as Type B quantities in addition to the applicable requirements stated above:

A. Package Markings
   49 CFR 172.310 - Radioactive material [Type B]

B. Shippers - General Requirements for Shipments and Packaging - **49 CFR 173**
   1. **49 CFR 173.25** - Requirements for use and labeling of overpacks
   2. **49 CFR 173.403** - Definitions
   3. **49 CFR 173.411** - General design requirements
   4. **49 CFR 173.413** - Additional design requirements for Type B packages

5. **49 CFR 173.416** - Authorized Type B packages [includes packaging certification requirements]
6. **49 CFR 173.471** - Additional requirements for Type B packages approved by NRC

Sample Shipping Documents, Placards and Labels

Hazard Communications for Class 7 (Radioactive) Materials

DOT Shipping Papers (49 CFR 172.200-205)

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

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

Some Special Considerations/Exceptions for Shipping Paper Requirements

! Shipments of Radioactive Material, excepted packages, under UN2910 (e.g., Limited Quantity, Empty packages, and Radioactive Instrument and Article), are excepted from shipping papers. For limited quantities (§173.421), this is only true if the limited quantity is not a hazardous substance (RQ) or hazardous waste (40 CFR 262)

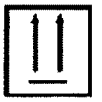
! Shipping papers must be in the pocket on the left door, or readily visible to person entering driver's compartment and within arm's reach of the driver

! For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, be designated by an "X" (or "RQ") in the hazardous material column, or be highlighted in a contrasting color

Hazard Communications for Class 7 (Radioactive) Materials

Marking Packages (49 CFR 172.300-338)

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

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

Some Special Considerations/Exceptions for Marking Requirements

! Marking is required to be: (1) durable, (2) printed on a package, label, tag, or sign, (3) unobscured by labels or attachments, (4) isolated from other marks, and (5) be representative of the hazmat contents of the package

! Limited Quantity (§173.421) packages and Articles Containing Natural Uranium and Thorium (§173.426) must bear the marking "radioactive" on the outside of the inner package or the outer package itself, and are excepted from other marking. The excepted packages shipped under UN 2910 must also have the accompanying statement that is required by §173.422.

! Empty (§173.428) and Radioactive Instrument and Article (§173.424) packages are excepted from marking

! Shipment of LSA or SCO required by §173.427 to be consigned as exclusive use are excepted from marking except that the exterior of each nonbulk package must be marked "**Radioactive-LSA**" or "**Radioactive-SCO**," as appropriate. Examples of this category are domestic, strong-tight containers with less than an A_2 quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52.

! For bulk packages, marking may be required on more than one side of the package (see 49 CFR 172.302(a))

Hazard Communications for Class 7 (Radioactive) Materials

Labeling Packages (49 CFR 172.400-450)

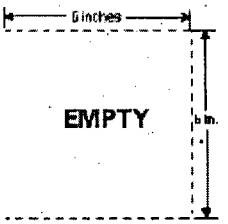
NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Placement of Radioactive Labels

! Labeling is required to be: (1) placed near the required marking of the proper shipping name, (2) printed or affixed to the package surface (not the bottom), (3) in contrast with its background, (4) unobscured by markings or attachments, (5) within color, design, and size tolerance, and (6) representative of the HAZMAT contents of the package

! For labeling of radioactive materials packages, two labels are required on opposite sides excluding the bottom

Determination of Required Label

Size: *Sides:* ≥ 100 mm (3.9 in.) *Border:* 5-6.3 mm (0.2-0.25 in.)	 49 CFR 172.436	 49 CFR 172.438	 49 CFR 172.440	 49 CFR 172.450
Label	**WHITE-I**	**YELLOW-II**	**YELLOW-III**	**EMPTY LABEL**
Required when:	Surface radiation level < 0.005 Mev/hr (0.5 mem./hr)	0.005 Mev/hr (0.5 mem./hr) < surface radiation level ≤ 0.5 Mev/hr (50 mem./hr)	0.5 Mev/hr (50 mem./hr) < surface radiation level ≤ 2 Mev/hr (200 mem./h) [Note: 10 Mev/hr (1000 mem./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 Mev/hr (0.05 mem./hr)]	**TI ≤ 1** [1 meter dose rate < 0.01 Mev/hr (1 mem./hr)]	**TI ≤ 10** [1 meter dose rate < 0.1 Mev/hr (10 mem./hr)] [Note: There is no package TI limit for exclusive-use]	
Notes:	! Any package containing a Highway Route Controlled Quantity (HRCQ) must bear YELLOW-III label ! Although radiation level transport indices (TIs) are shown above, for fissile material, the TI is typically determined on the basis of criticality control			

Content on Radioactive Labels

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

Some Special Considerations/Exceptions for Labeling Requirements

! For materials meeting the definition of another hazard class, labels for each secondary hazard class need to be affixed to the package. The subsidiary label may not be required on opposite sides and must not display the hazard class number

! Radioactive Material, excepted packages, under UN2910 (e.g., Limited Quantity, Empty packages, and Radioactive Instrument and Article), are excepted from labeling. However, if the excepted quantity meets the definition for another hazard class, it is re-classed for that hazard. Hazard communication requirements for the other class are required

! Labeling exceptions exist for shipment of LSA or SCO required by § 173.427 to be consigned as exclusive use

! The "Cargo Aircraft Only" label is typically required for radioactive materials packages shipped by air [§ 172.402(c)]

Hazard Communications for Class 7 (Radioactive) Materials

Placarding Vehicles (49 CFR 172.500-560)

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

Visibility and Display of Radioactive Placard

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

Conditions Requiring Placarding

- Placards are required for any vehicle containing package with a RADIOACTIVE Yellow-III label
- Placards are required for shipment of LSA or SCO required by §173.427 to be consigned as exclusive use. Examples of this category are domestic, strong-tight containers with less than an A_2 quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52. Also, for bulk packages of these materials, the orange panel *marking* with the UN identification number is not required.
- Placards are required any vehicle containing package with a Highway Route Controlled Quantity (HRCQ). In this case, the placard must be placed in a square background as shown below (see §173.507(a))

Radioactive Placard

Size Specs:

Sides: ≥ 273 mm (10.8 in.)

Solid line inner border: About 12.7 mm (0.5 in.) from edges

Lettering: ≥ 41 mm (1.6 in.)

Square for HRCQ: 387mm (15.25 in.) outside length by 25.4 mm (1 in.) thick

49 R CF 172 .556

RADIOACTIVE PLACARD (Domestic)

Base of yellow solid area: 29 ± 5 mm (1.1 ± 0.2 in.) above horizontal centerline

IAE 5 5) ASS (198 para 6. 443-444

RADIOACTIVE PLACARD (International)

See CF 172.527 AND 556 49 R

RADIOACTIVE PLACARD FOR HIGHWAY ROUTE CONTROLLED QUANTITY
(either domestic or international placard could be in middle)

Some Special Considerations/Exceptions for Placarding Requirements

- Domestically, substitution of the UN ID number for the word "RADIOACTIVE" on the placard is prohibited for Class 7 materials. However, some import shipments may have this substitution in accordance with international regulations.
- Bulk packages require the orange, rectangular panel marking containing the UN ID number, which must be placed adjacent to the placard (see §172.332) [NOTE: except for LSA/SCO exclusive use under §173.427, as above]
- If placarding for more than one hazard class, subsidiary placards must not display the hazard class number. Uranium Hexafluoride (UF_6) shipments ≥ 454 kg (1001 lbs) require both RADIOACTIVE and CORROSIVE (Class 8) placarding
- For shipments of radiography cameras in convenience overpacks, if the overpack does not require a RADIOACTIVE - YELLOW III label, vehicle placarding is not required (regardless of the label which must be placed on the camera)

Minimum Required Packaging For Class 7 (Radioactive) Materials

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

Quantity:	< 70 Bq/g (< 0.002 • 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]**

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

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

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

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

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

Package and Vehicle Contamination Limits (49 CFR 173.443)

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

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

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

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

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

Deviation from Basic Limits	Regulation 49 CFR §§	Applicable Location and Conditions Which must Be Met:
10 times the basic limits	173.443(b) and 173.443(c) Also see 177.843 (highway)	On any external surface of a package in an **exclusive use shipment, during transport** including end of transport. Conditions include: (1) Contamination levels at beginning of transport must be below the basic limits. (2) Vehicle must not be returned to service until radiation level is shown to be ≤ 0.005 Mev/hr (0.5 mem./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 Mev/hr (10 mem./hr) at the surface, or 0.02 Mev/hr (2 mem./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 Mev/hr (0.5 mem./hr) at any external surface. (3) Notice in §173.422(a)(4) must accompany shipment. (4) Package is in unimpaired condition & securely closed to prevent leakage. (5) Labels are removed, obliterated, or covered, and the "empty" label (§172.450) is affixed to the package.

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

DATE	P.O. NO.	SHIPPER NO.
SHIP DATE		

CONSIGNEE	SHIPPER/CONSIGNOR (FROM)
RED E. WAITING	**ABC PAVING COMPANY**
DEF PAVING INTERNATIONAL	**456 MAIN STREET**
123 DIRT ROAD	**ANY OTHER TOWN, USA 67890**
ANYTOWN, USA 12345	

PHONE NO.	EMERGENCY RESPONSE NUMBER (REQUIRED IN HM COLUMN MARKED)	ROUTE
	123-456-7890	

Number of Packages	HM *	Kind of Packaging, Description of Articles, Special Marks and Exceptions	Weight (lb)	Class or Rate Ref.	Cube (Optional)
1	**x**	**RQ, Radioactive Material, Type A package,**			
		Special Form, 7, UN3332			
		Cs-137, 0.30 GBq (8.0 mCi)			
		Am-241, 1.48 GBq (40 mCi)			
		Radioactive Yellow II Label, TI = 0.3			
		Dim 35 x 45 x 78 cm			
		Emergency Contact: (123) 456-7890			

THIS IS TO CERTIFY THAT THE ABOVE-NAMES MATERIALS ARE PROPERLY CLASSIFIED, DESCRIBED, PACKAGED, MARKED, AND LABELED AND ARE IN PROPER CONDITION FOR TRANSPORTATION ACCORDING TO THE APPLICABLE REGULATIONS OF THE DEPARTMENT OF TRANSPORTATION.

SHIPPER/CONSIGNOR	CARRIER
WANDA SHIPPITT	**SB FREIGHTWAYS**
AUTHORIZED SIGNATURE DATE	AUTHORIZED SIGNATURE

Appendix T

Model Waste Management Procedures

Model Waste Management Procedures

Model Waste Disposal Program

General Guidelines

A. All radioactivity labels must be defaced or removed from containers and packages prior to disposal. If non-radioactive waste is compacted, all radioactivity labels that are visible in the compacted mass must be defaced or removed.
B. Remind workers that non-radioactive waste should not be mixed with radioactive waste.
C. 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 operating and emergency procedures.
D. Evaluate 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.
E. Waste management program should include waste handling procedures. Also, procedures should be available for well logging personnel who may collect waste from areas of use to bring to the storage area for eventual disposal.

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

A. Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.
B. Short-lived waste should be segregated from long-lived waste (half-life greater than 120 days) at the source.
C. Waste should be stored in suitable well-marked containers and the containers should provide adequate shielding.
D. Liquid and solid wastes must be stored separately.
E. When the waste container is full, it should be sealed. The sealed container should be identified with a label affixed or attached to it.
F. 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.
G. The contents of the container should be allowed to decay for at least 10 half-lives of the longest-lived radioisotope in the container. The decay interval beginning at the time the radioactive waste container is sealed and placed in storage for DIS should be used for calculations and projected removal times.
H. Prior to disposal as ordinary trash, each container should be monitored as follows:
    1. Check the radiation detection survey meter for proper operation.
    2. Survey the contents of each container in a low background area.
    3. Remove any shielding from around the container.
    4. Monitor all surfaces of the container.
    5. 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.
    6. If the surveys indicate residual radioactivity, return the container to DIS area and contact the RSO for further instructions.
I. 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.

Model Procedure for Disposal of Liquids into Sanitary Sewerage

A. Confirm that the liquid radioactive waste containing radioactive material being discharged is soluble or readily dispersible in water.
B. Calculate the amount of each radioisotope that can be discharged by using the information from prior, similar discharges and the information in **12VAC5-481-3690**.
C. Make sure that the amount of each radioisotope does not exceed the monthly and annual discharge limits specified in **12VAC5-481-930** and **12VAC5-481-3690**.
D. Record the date, radioisotope(s), estimated activity of each radioisotope, location where the material is discharged, and the initials of the individual discharging the radioactive waste.
E. Liquid radioactive waste must be discharged only via designated locations.
F. Discharge radioactive liquid waste slowly with water running from the faucet to dilute it.
G. Survey the designated disposal locations and surrounding work surfaces to confirm that no residual material or contamination remains.
H. Prior to leaving the area, decontaminate all areas or surfaces, if found to be contaminated.
I. Maintain disposal records that identify each radioisotope and its quantity and the concentration that is released into the sanitary sewer system.

Appendix U

Well Owner/Operator Agreement

Well Owner/Operator Agreement

TERMS AND CONDITIONS

For good and valuable consideration received, Customer (as identified on the face of this document) and [Insert Company Name] (hereafter "*Insert Company Name Abbreviation*") agree as follows:

A. CUSTOMER REPRESENTATION - Customer warrants that the well is in proper condition to receive the services, equipment, products, and materials to be supplied by [Insert Company Name Abbreviation]

B. PRICE AND PAYMENT - The services, equipment, products, and/or materials to be supplied hereunder are priced in accordance with [Insert Company Name Abbreviation] current price list. All prices are exclusive of taxes. If Customer does not have an approved open account with [Insert Company Name Abbreviation], all sums due are payable in cash at the time of performance of services or delivery of equipment, products, or materials. If Customer has an approved open account, invoices are payable on the [Insert Number] day after the date of the invoice. Customer agrees to pay interest on any unpaid balance for the date payable until paid at the highest lawful contract rate applicable, but never to exceed [Insert Number]% per annum. In the event [Insert Company Name Abbreviation] employs an attorney for collection of any account, Customer agrees to pay attorney fees of [Insert Number]% of the unpaid account, plus all collection and court costs.

C. RELEASE AND INDEMNITY - CUSTOMER AGREES TO RELEASE [Insert Company Name Abbreviation] FROM ANY AND ALL LIABILITY FOR ANY AND ALL DAMAGES WHATSOEVER TO PROPERTY OF ANY KIND OWNED BY, IN THE POSSESSION OF, OR LEASED BY CUSTOMER AND THOSE PERSONS AND ENTITIES. CUSTOMER HAS THE ABILITY TO BIND BY CONTRACT. CUSTOMER ALSO AGREES TO DEFEND, INDEMNIFY AND HOLD [Insert Company Name Abbreviation] HARMLESS FROM AND AGAINST ANY AND ALL LIABILITY, CLAIMS, COSTS, EXPENSES, ATTORNEY FEES AND DAMAGES WHATSOEVER FOR PERSONAL INJURY, ILLNESS, DEATH, PROPERTY DAMAGE AND LOSS RESULTING FROM: LOSS OF WELL CONTROL; SERVICES TO CONTROL A WILD WELL WHETHER UNDERGROUND OR ABOVE THE SURFACE; RESERVOIR OR UNDERGROUND DAMAGE; DAMAGE TO OR LOSS OF OIL, GAS, OTHER MINERAL SUBSTANCES OR WATER; SURFACE DAMAGE ARISING FROM UNDERGROUND DAMAGE; DAMAGE TO OR LOSS OF THE WELL BORE; SUBSURFACE TRESPASS OR ANY ACTION IN THE NATURE THEREOF; FIRE; EXPLOSION; SUBSURFACE PRESSURE; RADIOACTIVITY; AND POLLUTION AND ITS CLEANUP AND CONTROL. CUSTOMER'S RELEASE, DEFENSE, INDEMNITY AND HOLD HARMLESS OBLIGATIONS WILL APPLY EVEN IF THE LIABILITY AND CLAIMS ARE CAUSED BY THE SOLE, CONCURRENT, ACTIVE OR PASSIVE NEGLIGENCE, FAULT, OR STRICT LIABILITY OF ONE OR MORE MEMBERS OF THE [Insert Company Name Abbreviation], THE UNSEAWORTHINESS OF ANY VESSEL OR ANY DEFECT IN THE DATA PRODUCTS, SUPPLIES, MATERIALS OR EQUIPMENT FURNISHED BY [Insert Company Name Abbreviation]. [Insert Company Name Abbreviation] IS DEFINED AS [Insert Company Name Abbreviation] ITS PARENT, SUBSIDIARY, AND AFFILIATED COMPANIES AND ITS/THEIR OFFICERS, DIRECTORS, EMPLOYEES, AND AGENTS. CUSTOMER'S RELEASE, DEFENSE, INDEMNITY AND HOLD HARMLESS OBLIGATIONS APPLY WHETHER THE PERSONAL INJURY, ILLNESS, DEATH, PROPERTY DAMAGE OR LOSS IS SUFFERED BY ONE OR MORE MEMBERS OF THE [Insert Company Name Abbreviation], CUSTOMER, OR ANY OTHER PERSON OR ENTITY, AND THE CUSTOMER WILL SUPPORT SUCH OBLIGATIONS ASSUMED

HEREIN WITH LIABILITY INSURANCE TO THE MAXIMUM EXTENT ALLOWED BY APPLICABLE LAW.

D. EQUIPMENT LIABILITY - Customer shall at its risk and expense attempt to recover any [Insert Company Name Abbreviation] equipment lost or lodged in the well. If the applicant is recovered and reputable, Customer shall pay the repair costs, unless caused by [Insert Company Name Abbreviation] sole negligence. If a radioactive source becomes lost or lodged in the well, Customer shall meet all requirements of **12VAC5-481-3160** of the **12VAC5-481, 'Virginia Radiation Protection Regulations'** and any other applicable laws or regulations concerning retrieval or abandonment and shall permit [Insert Company Name Abbreviation] to monitor the recovery or abandonment efforts all at no risk or liability to [Insert Company Name Abbreviation]. Customer shall be responsible for damages to or loss of [Insert Company Name Abbreviation] equipment, products, and materials while in transit aboard Customer-applied transportation, even if such is arranged by [Insert Company Name Abbreviation] at Customer's request, and during loading and unloading from such transport. Customer will also pay for the repair or replacement of [Insert Company Name Abbreviation] equipment damaged by corrosion or abrasion due to well effluents.

E. LIMITED WARRANTY - [Insert Company Name Abbreviation] warranty only applies to the equipment, products, and materials supplied under this agreement and that same are free from defects in workmanship and materials for one year from date of delivery. THERE ARE NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS OR OTHERWISE BEYOND THOSE STATED IN THE IMMEDIATELY PRECEDING SENTENCE. [Insert Company Name Abbreviation] sole liability and Customer's exclusive remedy in any cause of action (whether in contract, tort, breach of warranty or otherwise) arising out of the sale, lease or use of any equipment, products, or materials is expressly limited to the replacement of such on their return to [Insert Company Name Abbreviation] or, at [Insert Company Name Abbreviation] option, to the allowance to Customer of credit for the cost of such items. In no event shall [Insert Company Name Abbreviation] be liable for special, incidental, indirect, consequential, or punitive damages. Because of the uncertainty of variable well conditions and the necessity of relying on fads and supporting services furnished by other, [Insert Company Name Abbreviation] IS UNABLE TO GUARANTEE THE EFFECTIVENESS OF THE EQUIPMENT, MATERIALS, OR SERVICE, NOR THE ACCURACY OF ANY CHART INTERPRETATION, RESEARCH ANALYSIS, JOB RECOMMENDATION OR OTHER DATA FURNISHED BY [Insert Company Name Abbreviation]. [Insert Company Name Abbreviation] personnel will use their best efforts in gathering such information and their best judgment in interpreting it, but Customer agrees that [Insert Company Name Abbreviation] shall not be liable for and CUSTOMER SHALL INDEMNIFY [Insert Company Name Abbreviation] AGAINST ANY DAMAGES ARISING FROM THE USE OF SUCH INFORMATION, even if such is contributed to by [Insert Company Name Abbreviation] negligence or fault. [Insert Company Name Abbreviation] also does not warrant the accuracy of data transmitted by electronic process, and [Insert Company Name Abbreviation] will not be responsible for accidental interception of such data by third parties.

F. GOVERNING LAW - The validity, interpretation and construction of this agreement shall be determined by the laws of the jurisdiction where the services are performed or the equipment or materials are delivered.

G. WAIVER - Customer agrees to waive the provisions of the Virginia Consumer Protection Act or any similar Federal or State act to the extent permitted by law.

H. MODIFICATIONS - Customer agrees that [Insert Company Name Abbreviation] shall not be bound by any modifications to this agreement, except where such modification is made in writing by a duly authorized executive officer of [Insert Company Name Abbreviation]. Requests for modifications should be directed to [Insert Name and Title].

Appendix V

Actions to be Taken if a Sealed Source is Ruptured

Actions to be Taken if a Sealed Source is Ruptured

12VAC5-481-3340 F requires immediate initiation of emergency procedures if there is evidence that a sealed source has ruptured or that licensed materials have caused contamination.

Your procedures should instruct logging personnel to:

- Notify immediately the RSO or other appropriate management personnel.
- Notify the well owner or operator as soon as possible.
- Notify the agency at the appropriate telephone number ((804) 864-8150 during business hours; (804) 674-2400 or (800) 468-8992 after hours. Identify the emergency as radiological).
- Secure and restrict access to the area until responsible individuals arrive.
- Instruct individuals on site not to take any unnecessary actions that could spread contamination.
- Minimize inhalation or ingestion of licensed material by using protective clothing and respirators.
- Discuss procedures for preventing the spread of contamination and for minimizing inhalation or ingestion with any potentially exposed personnel.
- Obtain suitable radiation survey instruments.

Commonwealth of Virginia
Radiation Protection Regulatory Guide

Guidance for Uses of Sealed Sources

EPI-720 K

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

EXECUTIVE SUMMARY

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

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

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

This VAREG, 'Guidance for Uses of Sealed Sources' has been developed to streamline the application process for a Sealed Source license. A copy of the application VDH form, 'Application for a Radioactive Material License Authorizing the Use of Sealed Sources' is located in **Appendix A** of this guide.

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

It typically takes 60-90 days for a license to be processed and issued if the application is complete. When submitting the application be sure to include the appropriate application fee listed in **12VAC5-491**.

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

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

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

  Please identify all attachments with the applicant's name and license number (if a renewal).
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original signed application along with attachments (if any).
- Submit the application fee (for new licenses only).
- Retain one copy of the licensee application and attachments (if any) for your future reference. You will need this information because the license will require that radioactive material be possessed and used in accordance with statements, representation, and procedures provided in the application and supporting documentation.

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

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ABBREVIATIONS

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

SS&D	Sealed Source and Devices Bulletin Board System (BBS)
SSDR	Sealed Source and Device Registration
Sv	Sievert
T1/2	Half-life
TEDE	Total effective dose equivalent
TI	Transportation Index
TLD	Thermoluminescent dosimeters
VDH	Virginia Department of Health
μCi	microcurie
%	percent

PURPOSE OF GUIDE

This document provides guidance to an applicant in preparing a sealed source license application for sources other than portable gauges, XRFs, or fixed gauges. It also provides on VDH's criteria for evaluating a sealed source license application. It is not intended to address the commercial aspects of manufacturing, distribution, and service of devices containing sealed sources. It does addresses radiation safety issues associated with sealed sources such as calibration and reference sources. If higher activity sources are being requested, consult with VDH staff for the appropriate guidance and application form.

This guide identifies information needed to complete VDH form, 'Application for a Radioactive Material License Authorizing the Use of Sealed Sources.' (**Appendix A**).

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

- **Rule**--references the requirements from **12VAC5-481 'Virginia Radiation Protection Regulations'** applicable to the item;
- **Criteria**--outlines the criteria used to judge the adequacy of the applicant's response;
- **Discussion**--provides additional information on the topic sufficient to meet the needs of most readers; and
- **Response from Applicant**--provides suggested response(s), offers the option of an alternative reply, or indicates that no response is needed on that topic during the licensing process.

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

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

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

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

LICENSES

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

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

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

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

12VAC5-481-630, Radiation protection programs, states that *"each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities"* and *"the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are...ALARA."* This section also requires that licensees review the content of the radiation protection program and its implementation annually.

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

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

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

WHO REGULATES AT FACILITIES IN THE COMMONWEALTH OF VIRGINIA?

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

Table 1. Who Regulates the Activity?

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

A current list of Agreement States (States that have entered into agreements with the NRC that give them the authority to license and inspect radioactive material used or possessed within their

borders), including names, addresses, and telephone numbers of responsible officials are maintained by the NRC Office of Federal and State Materials and Environmental Management Programs and is available on their website: http://nrc-stp.ornl.gov/.

MANAGEMENT RESPONSIBILITY

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

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

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

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

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

APPLICABLE RULE

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

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

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

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

HOW TO FILE

Applicants for a materials license should do the following:

- Be sure to use the current guidance from VDH in preparing an application.
- Complete VDH form, 'Application for Radioactive Material License Authorizing the Use of Sealed Sources' (**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.

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

WHERE TO FILE

Applicants wishing to possess or use radioactive material in Commonwealth of Virginia are subject to the requirements of **12VAC5-481, 'Virginia Radiation Protection Regulations'** and must file a license application with:

Virginia Department of Health
Radioactive Materials Program
109 Governor Street, Room 730
Richmond, VA 23219

LICENSE FEES

The appropriate fee must accompany each application or license amendment request. Refer to **12VAC5-491** to determine the amount of the fee. VDH will not issue the new license prior to fee receipt. Once technical review has begun, no fees will be refunded. Application fees will be charged regardless of VDH's disposition of an application or the withdrawal of an application.

Licensees are also subject to annual fees; refer to **12VAC5-490**.

Direct all questions about VDH' fees or completion of **Item 10** of VDH form, ''Application for a
Radioactive Material License Authorizing the Use of Sealed Sources' **(Appendix A)** to: Virginia Department of Health,, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219 or call (804) 864-8150.

CONTENTS OF AN APPLICATION

Item 1: Type of Application

On the application check the appropriate box and, if appropriate, note the license number for renewal.

Response from Applicant:

Item 1 Type of Application (Check one box)
☐ New License ☐ Renewal License Number _____

Item 2: Name and Mailing Address of Applicant

List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent. A Post Office box number is an acceptable mailing address.

Notify the agency of changes in the mailing address.

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 Transfer of Control

Rule: 12VAC5-481-330, 12VAC5-481-450, 12VAC5-481-500

Criteria: Licensees must provide full information and obtain VDH's **written consent prior** to transferring ownership or control of the license, or, as some licensees call it, 'transferring the license'.

Discussion: Transfer of control may be the results of mergers, buyouts, or majority stock transfers. Although it is not VDH's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain prior VDH written consent. This is to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid licenses issued by VDH;
- Materials are properly handled and secured;
- Persons using these materials are competent and committed to implementing appropriate radiological controls;
- A clear chain of custody is established to identify who is responsible for final disposal of the possessed material; and
- Public health and safety are not compromised by the use of such materials.

Appendix C identifies the information to be provided about changes of ownership or transfer of control.

Notification of Bankruptcy Proceedings

Rule: 12VAC5-481-500

Criteria: Immediately following filing of voluntary or involuntary petition for bankruptcy, 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 all regulatory requirements. VDH needs to know when licensees are in bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled, and whether there are any public health and safety concerns (e.g.; contaminated facility). VDH shares the results of its determinations with other involved entities (e.g.; trustees), so that health and safety issues can be resolved prior to completion of bankruptcy proceedings.

Item 3: Person To Be Contacted Regarding Application

Criteria: Identify the individual who can answer questions about the application and include his or her telephone number.

Discussion: This is typically the proposed Radiation Safety Officer (RSO), unless the applicant has named a different person as the contact. The agency will contact this individual if there are questions about the application.

Notify the agency if the contact person or his or her telephone number changes so that the agency can contact the applicant or licensee in the future with questions, concerns, or information. This notice is 'for information only' and does not require a license amendment or a fee.

Response from Applicant:

Item 3. Person to Contact Regarding this Application
Contact's Telephone Number (Include Area Code)

Item 4: Address(es) Where Radioactive Material Will Be Used or Possessed

Rule: 12VAC5-481-450, 12VAC5-481-500

Criteria: Applicants must provide a specific address for each location where radioactive material will be used, stored, or dispatched.

Discussion: Specify the street address, city, and state or other descriptive address (e.g., on Highway 58, 5 miles east of the intersection of Highway 11E and State Route 16, Anytown, VA) for each facility at which licensed material will be used or stored. The descriptive address should be sufficient to allow a VDH inspector to find the use/storage location. **A Post Office Box address is not acceptable**. In addition, state whether the sealed sources will be used at temporary jobsites.

Response from Applicant:

Item 4 Address(es) where radioactive material(s) will be used or possessed. (Attach additional pages if necessary)		
	Address (Do not use Post Office box)	**Telephone Number** (Include area code)
☐ Used ☐ Stored ☐ Used and Stored		
☐ Used ☐ Stored ☐ Used and Stored		
☐ Used ☐ Stored ☐ Used and Stored		
Are sealed sources used at temporary jobsites?: ☐ Yes ☐ No		

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).

Note: As discussed later under "*Financial Assurance and Record keeping for Decommissioning*", licensees need to maintain permanent records on where licensed material was used or stored while the license was in force. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). For licensees, acceptable records are sketches or written descriptions of storage or use locations specifically listed on the license. Licensees do not need to maintain this information for temporary job sites or temporary storage locations where sources have never leaked.

Item 5: Radiation Safety Officer (RSO)

Rule: 12VAC5-481-450 A, 12VAC5-481-490 B, 12VAC5-481-2270

Criteria: RSO must have adequate training and experience. The RSO is responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

Discussion: The person responsible for the radiation protection program is called the RSO. The RSO needs independent authority to stop operations that he or she considers unsafe. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. VDH requires the name of the RSO on the license to ensure that licensee management has identified a qualified person and that the named individual knows of his or her designation as RSO. This individual should have specific training and experience in the use and handling of sealed sources.

Response from Applicant:

Item 5 Radiation Safety Officer (RSO) (Check both boxes)

☐ 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.

NAME: _____ TELEPHONE NUMBER: (Include area code) _____

AND

☐ 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.

Item 6: Authorized Users

Rule: 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-2260, 12VAC5-481-2270

Criteria: Authorized users (AUs) must have adequate training and experience.

Discussion: An AU is a person whose training and experience meet VDH's criteria. This individual is named on the license and uses or directly supervises the use of licensed material. AUs must ensure the proper use and security of the sealed sources. An AU is considered to be supervising the use of licensed material when he or she directs personnel in operations involving the material. Although the AU may delegate specific tasks to supervised users (e.g., maintaining records), he or she is still responsible for safe use of licensed material.

A trained individual must perform any operation that involves the removal of a sealed source from a device or maintenance and repair of a device that involves a sealed source. The trained 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. See **Appendix D** for suggested training topics. The following information will be required for AUs:

- Name of each trained individual who will perform the operations
- Outline of the instruction and training that each individual has received. The amount of time spent on each topic in the training should be specified.

Response from Applicant:

Item 6 Authorized Users (Check all that apply)
☐ 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.
Note: If requesting authorization to perform non-routine maintenance, submit outline of the instruction and training for individuals performing non-routine maintenance.

Note: Persons who will only use a sealed source and device, if applicable, under the supervision of the trained individual named in **Item 6** need no special training. These individuals should not be permitted to perform any maintenance or repair operations. Only trained individuals specifically named in **Item 6** shall perform such operations.

Item 7: Radioactive Material

Item 7.1: Sealed Sources

Rule: 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-840, 12VAC5-481-850, 12VAC5-481-860, 12VAC5-481-880, 12VAC5-481-3750

Criteria: Licensees will only be authorized for sealed sources and devices listed in the Sealed Source and Device Registry. Sealed sources and devices may be used only for the purposes for which they are designed and specified in an Sealed Source Device Registration (SSDR) Sheet.

Discussion: Each authorized radioisotope is listed on a VDH license by its element name, form, and the maximum amount the licensee may possess at any one time (maximum possession limit). Licensees must submit a license amendment and receive VDH authorization before they may make changes in the types, forms, and quantities of materials possessed.

Possession limits should be specified in megabecquerels (MBq) [millicuries (mCi)] or gigabecquerels (GBq) [curies (Ci)] for each radioisotope. Applicants should include in the possession limits requested the total estimated inventory, including licensed material in storage and maintained as radioactive waste. The requested possession limits for any radioisotope should be commensurate with the applicant's needs and facilities for safe handling. Applicants, when establishing their possession limits for radioactive materials with half lives greater than 120 days, should review the requirements for submitting a certification for financial assurance for decommissioning, see **Item 7.2.**

Consult with the proposed manufacturer or distributor to ensure that sources and devices conform to the sealed source and device designations registered with 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. Such changes may necessitate a custom review, increasing the time needed to process a licensing action. To ensure that applicants use sources and devices according to the registration certificates, they may want to get a copy of the certificate and review it or discuss it with the manufacturer.

A safety evaluation of sealed sources and devices is performed by NRC or another Agreement State before authorizing a manufacturer (or distributor) to distribute them to specific licensees. The safety evaluation is documented in a SSDR Certificate. SSDR Certificates contain sections on "*Conditions of Normal Use*" and "*Limitation and Other Considerations of Use*". These sections may include limitations derived from conditions imposed by the manufacturer or distributor, by particular conditions of use that would reduce radiation safety of the device, or by circumstances unique to the sealed source or device. Except as specifically approved by VDH, licensees are required to use the sealed source and devices according to their respective SSDR Certificates. Information on SSDR Certificates may be obtained through the agency, if necessary. Applicants must provide the manufacturer's name and model number for each requested sealed source so that the agency can verify that each, when applicable, has been evaluated in an SSDR Certificate.

The following will be required for each:

- The radioisotopes(s) that will be used.
- The manufacturer and model number of the sealed source that will be used.
- The quantity (activity) of radioactive material that will be in each sealed source. Provide the number of sources of sealed source that will be possessed, if known. If the total number for each type of source is unknown, provide an anticipated total.
- The manufacturer and model number of the device containing the sealed source-if applicable.
- The purpose for which each sealed source(s) will be used (e.g., state that possession of sealed sources will be used for commercial calibration of radiation survey instruments and/or personnel dosimetry).

Note: Unusual uses will be evaluated on a case-by-case basis and the authorized use condition will reflect approved uses.

Response from Applicant:

Item 7 Radioactive Material (Attach additional pages if necessary)	
Element and mass number	Chemical and Physical form: **SEALED SOURCE**
Source manufacturer and model number	Maximum activity per source
Device manufacturer and model number	Intended use

Item 7.2: Financial Assurance and Record Keeping for Decommissioning

Rule: 12VAC5-481-100, 12VAC5-481-450 C, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-1161

Criteria: Licensees possessing sealed sources containing radioactive material in excess of the limits specified in **12VAC5-481-450 C** must provide evidence of financial assurance for decommissioning.

Licensees are required to maintain, in an identified location, decommissioning records related to structures and equipment where sealed sources are used or stored and for any leaking sources. Licensees must transfer records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with **12VAC5-481-500** or to VDH before the license is terminated.

Discussion: The requirements for financial assurance are specific to the types and quantities of radioactive material authorized on a license. Most applicants and licensees do not need to comply with the financial assurance requirements because the thresholds for sealed sources are 3.7×10^6 gigabecquerels (100,000 curies) of cesium-137 or 3.7×10^3 gigabecquerels (100 curies) of americium-241 or californium-252. Since the standard license may not specify the maximum number of sealed sources that the licensee may possess (allowing the licensee flexibility in obtaining sealed sources as needed without amending its license), it may contain a condition requiring the licensee to limit its possession of sealed sources to quantities not requiring financial assurance for decommissioning. Applicants and licensees desiring to possess sealed sources exceeding the threshold amounts must submit evidence of financial assurance.

The same rule also requires that licensees maintain records important to decommissioning in an identified location. All sealed source licensees need to maintain records of structures and equipment where sealed sources are used or stored at locations specifically listed on the license. As-built drawings with modifications of structures and equipment shown as appropriate fulfill this requirement. If drawings are not available, licensees may substitute appropriate records concerning the areas and locations. In addition, if licensees have experienced unusual occurrences (e.g., leaking sources), they also need to maintain records about contamination that remains after cleanup or that may have spread to inaccessible areas.

For sealed source licensees whose sources have never leaked, acceptable records important to decommissioning are sketches or written descriptions of storage or use locations specifically listed on the license. Similar information need not be maintained for temporary job sites.

Licensees must transfer records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with **12VAC5-481-500** or to VDH before the license is terminated.

Reference: NRC Regulatory Guide 3.66 "*Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70 and 72*", is available from NRC at http://www.nrc.gov.

Item 8: Facilities and Equipment

Rule: 12VAC5-481-450, 12VAC5-481-630, 12VAC5-481-730, 12VAC5-481-840

Criteria: 12VAC5-481-450 states that an application will be approved if the applicant's proposed equipment and facilities are adequate to protect health and to minimize danger to life or property.
12VAC5-481-840 states that licensed material stored in an unrestricted area must be secured from unauthorized removal, and licensed materials in an unrestricted area and not in storage must be under the constant surveillance and immediate control of the licensee.

Discussion: The room or storage area in which the sealed source and device, if applicable, is located should be:

- Accessible only to persons authorized to use the sealed source or device and
- Locked when an authorized person is not physically present.

The room or storage area should be locked or secured when an authorized person is not present. The room or storage area cannot be considered a restricted area if it is accessible to unauthorized persons.

The key elements for applicants are ensuring compliance with public dose limits and maintaining adequate security and control over the sealed sources.

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;
- Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below; indicate whether the room is a restricted or unrestricted area as defined in **12VAC5-481-10**; 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., source storage safe, etc.).

Response from Applicant:

Item 8 Facilities And Equipment (Check box and attach diagram.)

☐ Diagrams of radioactive material storage area(s) are attached.

Item 9: Radiation Safety Program

Item 9.1: Audit Program

Rule: 12VAC5-481-450, 12VAC5-481-630, 12VAC5-481-990

Criteria: Licensees must review the content and implementation of their radiation protection programs annually to ensure the following:

- Compliance with VDH and DOT regulations, and the terms and conditions of the license;
- Occupational doses and doses to members of the public are as low as reasonably achievable (ALARA) *(***12VAC5-481-630***)*; and
- Records of audits and other reviews of program content are maintained for 3 years.

Discussion: 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 F contains a suggested audit program that is acceptable to VDH. All areas indicated in **Appendix F** may not be applicable to every licensee and may not need to be addressed during each audit.

12VAC5-481-990 requires licensees to maintain records of audits and other reviews of program content and implementation. The agency has found audit records that contain the following information to be acceptable: date of audit, name of person(s) who conducted audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up.

Response From Applicant:

Item 9.1 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 9.2: Radiation Monitoring Instruments

Rule: 12VAC5-481-450, 12VAC5-481-730, 12VAC5-481-740, 12VAC5-481-750, 12VAC5-481-900, 12VAC5-481-930, 12VAC5-481-1000

Criteria: Licensees must possess, or have access to, radiation monitoring instruments that are necessary to protect health and minimize danger to life or property.

Discussion: Licensees shall possess, or have access to, calibrated radiation measurement instruments or licensed services to perform, as necessary the following:

- Package receipt surveys
- Sealed source leak tests
- Unrestricted area dose rate measurements

For the purposes of this document, survey instruments are defined as any device used to measure the radiation exposure or contamination levels at a licensed facility. Survey instruments that may be used to perform these measurements include exposure rate meters or contamination survey meters. Survey instruments that will be available for use or that the licensee intends to purchase should be listed and descriptions of the instrumentation prior to starting licensed activities. The description should include type of instrument and detector and its intended purpose.

VDH requires that calibrations be performed by the instrument manufacturer or a person specifically authorized by VDH, NRC, or another Agreement State. Applicants seeking

authorization to perform survey instrument calibrations shall submit procedures for review. **Appendix E** provides information about instrument specifications and calibration procedures.

Response from Applicant:

Item 9.2 Radiation Monitoring Instruments (Check all that apply)

☐ We will have access to a survey meter that meets the Criteria in the section titled 'Radiation Monitoring Instruments' in VAREG 'Guidance for Uses of Sealed Sources'. (Description attached)

OR

☐ We will possess a survey meter that meets the Criteria in the section titled 'Radiation Monitoring Instruments' in VAREG 'Guidance for Uses of Sealed Sources'.

AND ONE OF THE FOLLOWING

☐ Each survey meter will be calibrated by an organization licensed by VDH, NRC, or another Agreement State to perform survey meter calibrations.

OR

☐ We will implement the model survey meter calibration program published in Appendix E in VAREG 'Guidance for Uses of Sealed Sources'.

OR

☐ We will submit alternative calibration procedures for agency review. (Procedures are attached)

Item 9.3: Material Receipt and Accountability

Rule: 12VAC5-481-10, 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-840, 12VAC5-481-900, 12VAC5-481-980, 12VAC5-481-1060, 12VAC5-481-1080, 12VAC5-481-1090

Criteria: Licensees must do the following:

- Maintain records of receipt, transfer, and disposal for all sealed sources; and
- Conduct physical inventories at intervals not to exceed 6 months (or some other interval justified by the applicant) to account for all sealed sources.

Discussion: Licensees are required to maintain records of receipt, transfer, and disposal of licensed material. Loss, theft, or misplacement of radioactive material can occur; therefore control and accountability of sealed sources must be ensured. Licensees who use and/or possess sealed sources are required by license conditions to perform inventories of sealed sources every six months. Sealed sources that are not in use may be placed in storage and shall be inventoried at least every 6 months.

Inventory records should be maintained and contain the following types of information:

- Radionuclide and amount (in units of becquerels or curies) of radioactive material in each sealed source;
- Manufacturer's name, model number, and serial number (if appropriate) of each device containing radioactive material;
- Location of each sealed source and device; and
- Date of the inventory.

'Cradle to Grave' Accountability refers to maintaining the radioactive material from the moment it becomes a part of your organization (whether through creation there, delivered to company, etc) through performing the quarterly inventories (ensuring the material's location, etc) until it leaves your organization (through shipment, disposal on/off site, etc)

Response from Applicant:

Item 9.3 Material Receipt And Accountability (Check one box)

☐ We will conduct physical inventories 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 sealed sources have been lost, stolen, or misplaced. (Procedures are attached)

Item 9.4: Occupational Dosimetry

Rule: 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-680, 12VAC5-481-700, 12VAC5-481-710, 12VAC5-481-750, 12VAC5-481-760, 12VAC5-481-990, 12VAC5-481-1000, 12VAC5-481-1020, 12VAC5-481-1040, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1130, 12VAC5-481-1140, 12VAC5-481-2260, 12VAC5-481-2270

Criteria: Applicants must do either of the following:

- Provide dosimetry processed and evaluated by a National Voluntary Laboratory Accreditation Program (NVLAP) approved processor that is exchanged at a frequency recommended by the processor.

OR

- Maintain, for inspection by VDH, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits as shown in **Table 2**.

Table 2: Occupational Dose Limits For Adults

Occupational Dose Limits for Adults (12VAC5-481-640)	
Body Location	Dose (Annual)
Total Effective Dose Equivalent (TEDE)	0.05 Sv (5 Rem)
Dose to the skin of the whole body or any extremity*	0.5 Sv (50 Rem)
Dose to lens of the eyes	0.15 Sv (15 Rem)
*Extremities includes the arms below the elbows and the legs below the knees	

Discussion: Under conditions of routine use, many sealed source users do not require a personnel monitoring device (dosimetry). If a written evaluation demonstrates that sealed source users are not likely to exceed 10 percent of the applicable limits, users are not required to have personnel dosimetry. **Appendix I Part I** provides guidance on preparing this written evaluation.

Licensees who do provide personnel monitoring use either film badges, optically stimulated luminescent (OSLs) dosimetry or thermoluminescent dosimeters (TLDs) that are supplied by a NVLAP-approved processor. Applicants should verify that the processor is NVLAP-approved. Consult the NVLAP-approved processor for its recommendations for exchange frequency and proper use.

Response from Applicant:

Item 9.4 Occupational Dosimetry (Check one)
☐ We will maintain, for inspection by the agency, 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 **12VAC5-481-640**.
OR
☐ We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged at a frequency recommended by the processor

Reference: National Institute of Standards and Technology (NIST) Publication 810, "*National Voluntary Laboratory Accreditation Program Directory*", is published annually and is available for purchase from United States Government Printing Office and on the Internet at the following address: http://nvl.nist.gov/

Item 9.5: Public Dose

Rule: 12VAC5-481-10, 12VAC5-481-630, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-840, 12VAC5-481-1050, 12VAC5-481-1110, 12VAC5-481-3070

Criteria: Licensees must do the following:

- Ensure that sealed sources will be used, transported, and stored in such a way that members of the public will not receive more than 1 millisievert (100 millirem) in one year, and the dose in any unrestricted area will not exceed 0.02 millisievert (2 millirem) in any one hour, from licensed operations.
- Control and maintain constant surveillance over sealed sources that are not in storage and secure sealed sources from unauthorized removal or use.

Discussion: "*Public dose*" is defined in **12VAC5-481-10** as the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee. Public dose excludes doses received from background radiation and from medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individuals assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) the individual is in when the dose is received.

Members of the public include persons who live, work, or may be near locations where sealed sources are used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where sealed sources are used or stored.

Operating and emergency procedures regarding security and surveillance specified under that section of this document should be sufficient to limit the exposure to the public during use or storage and after accidents. Public dose is controlled, in part, by ensuring that sealed sources not in use are stored securely (e.g., stored in a locked area) to prevent unauthorized access or use. If sealed sources are not in storage, then authorized users must maintain constant surveillance to ensure that members of the public, who could be co-workers, cannot get near the sealed sources and thus receive unneeded radiation exposure.

Public dose is also affected by the choice of storage location and conditions. Since a sealed source presents a radiation field during storage, it must be stored so that the radiation level 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. Use the concepts of time, distance, and shielding when choosing a permanent or temporary storage location. Decreasing the time spent near an unshielded sealed source, increasing the distance from the unshielded sealed source, and using shielding (i.e., brick, concrete, lead, or other solid walls) will reduce the radiation exposure. As a rule of thumb, sealed sources should be stored as far away as possible from areas that are occupied by members of the public.

Licensees can determine the radiation levels adjacent to the storage location either by calculations or a combination of direct measurements and calculations using any 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, and occupancy factors to account for the actual presence of the member of the public and of the sealed sources used. See **Part 2** of **Appendix I** for examples.

If, after making an initial evaluation, a licensee makes changes affecting the storage area (e.g., changing the location of sealed sources within the storage or use area, removing shielding, adding sealed sources, changing the occupancy of adjacent areas, moving the storage area to a new location), then the licensee must ensure that sealed sources are properly secured, perform a new evaluation to ensure that the public dose limits are not exceeded, and take corrective action, as needed.

Response from Applicant:

Item 9.5 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 9.6: Operating and Emergency Procedures

Rule: 12VAC5-481-450, 12VAC5-481-630, 12VAC5-481-740, 12VAC5-481-840, 12VAC5-481-850, 12VAC5-481-860, 12VAC5-481-870, 12VAC5-481-880, 12VAC5-481-890, 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-2280

Criteria: Operating and emergency procedures must be developed to minimize risks of loss or theft as well as to ensure safe use of radioactive material. The agency considers security of sealed sources extremely important and lack of security is a significant violation for which licensees are fined.

Discussion: Operating and emergency procedures shall contain the following elements:

- Instructions for using the sealed sources and device-if applicable and performing routine maintenance, according to the manufacturer's recommendations and instructions;
- Instructions for maintaining security during use, storage, and transportation;
- Instructions for keeping the sealed source under control and immediate surveillance during use;
- Instructions for keeping radiation exposures ALARA.

Notify the agency when sealed sources are lost or stolen. Refer to **12VAC5-481-1090, 12VAC5-481-1100,** and **12VAC5-481-1110** for a description of when and where notifications are required.

Response from Applicant:

Item 9.6 Operating And Emergency Procedures (Check box)
☐ Operating and emergency procedures will be developed, implemented, and maintained, and will meet Criteria in the section titled 'Operating and Emergency Procedures' in VAREG 'Guidance for Uses of Sealed Sources'. (Procedures are attached)

Item 9.7: Leak Tests

Rule: 12VAC5-481-740, 12VAC5-481-1010, 12VAC5-481-1150

Criteria: VDH requires testing to determine whether there is any radioactive leakage from the source in the device. Records of leak tests results must be maintained.

Discussion: The agency finds testing to be acceptable if it is conducted by an organization approved by VDH, NRC, or another Agreement State or according to procedures approved by VDH.

A licensee will be required to ensure performance of leak tests at intervals approved by the NRC or another Agreement State and as specified by the SSDR Certificate. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 μCi) of radioactivity.

Manufacturers, consultants, and other organizations may be authorized by VDH, NRC, or another Agreement State either to perform the entire leak test sequence for other licensees or to provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample according to the sealed source manufacturer's (distributor's) and the kit supplier's instructions and return it to the kit supplier for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. Licensees may also be authorized to conduct the entire leak test sequence themselves by adopting the procedures in **Appendix J** or submitting alternative procedures.

Response from Applicant:

Item 9.7 Leak Tests (Check one box)

☐ Leak tests will be performed by an organization authorized by VDH, 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, NRC, or another Agreement State to provide leak test kits to other licensees according to kit supplier's instructions.

List name and license number of organization authorized to perform or analyze leak test (Specify whether VDH, NRC, or another 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 another Agreement State.

OR

☐ We will perform leak testing and sample analysis and will follow the procedures in Appendix J of VAREG 'Guidance for Uses of Sealed Sources'. (Procedures are attached)

OR

☐ We will submit alternative procedures. (Procedures are attached)

Item 9.8: Maintenance and Repair

Rule: 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-630

Criteria: Radiation safety procedures must consider the possibility of receiving exposures to the whole body, as well as to the hands, from handling the sealed sources during maintenance and repair. Licensees should keep such exposures ALARA and ensure that the device functions as designed and source integrity is not compromised.

Discussion: Licensees may need to clean and maintain devices containing sealed sources according to manufacturer recommendations and instructions. Written procedures provided by the device manufacturer should be followed. If a procedure other than that provided by the device manufacturer, submit a proposed procedure.

Response from Applicant:

Item 9.8 Maintenance and Repair (Check one box)

☐ We will send the device to the manufacturer or other person authorized by VDH, NRC, or another Agreement State to perform maintenance or repair operations.

OR

☐ We will implement and maintain procedures for maintenance of devices containing sealed sources according to each manufacturer's recommendations and instructions.

OR

☐ We will develop, implement, and maintain procedures for maintenance of devices containing sealed sources. (Procedures are attached)

OR

☐ We will only possess sealed sources not in devices. No maintenance or repair is required.

Item 9.9: Transportation

Rule: 12VAC5-481-100, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-2980, 12VAC5-481-3070, 12VAC5-481-3100, 49 CFR Parts 171-178

Criteria: Applicants must develop, implement, and maintain safety programs for public transport of radioactive material to ensure compliance with DOT regulations.

Discussion: If authorization has been requested in the application to use sealed sources at a temporary jobsite, the applicant must consider DOT regulations.

Response from Applicant:

Item 9.9 Transportation
No response is needed during the license process; this issue will be reviewed during inspection.

Item 9.10: Waste Management

Rule: 12VAC5-481-100, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-910, 12VAC5-481-1060

Criteria: Licensed materials must be disposed of in accordance with VDH requirements by transfer to an authorized recipient. Appropriate records must be maintained.

Discussion: The usual disposal option is to transfer the licensed material to an authorized recipient. Authorized recipients are the original supplier of the sealed source or device, a commercial firm licensed by VDH, 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.

Response from Applicant:

Item 9.10 Waste Management (Check box)
☐ We will transfer the sealed source or device containing the sealed source to the manufacturer or a specifically licensed recipient for disposal.

Item 9.11: Termination of Activities

Rule: 12VAC5-481-450 C, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-980, 12VAC5-481-1161

Criteria: The licensee must do the following:

- Notify the agency in writing, within 60 days of the decision to permanently discontinue all activities involving materials authorized under the license.
- Notify the agency in writing, within 60 days, when principal activities have not been conducted for a period of 24 months.

- Certify the disposition of licensed materials by submission of VDH form 'Certificate of Disposition of Materials'. (See **Appendix B**).
- Before a license is terminated, send the records important to decommissioning (as required by **12VAC5-481-571**) to the agency. If licensed activities are transferred or assigned in accordance with **12VAC5-481-500**, transfer records important to decommissioning to the new licensee.

Discussion: For guidance on the disposition of licensed material, see the **Item 9.10 Waste Management**. For guidance on decommissioning records, see the section on **Item 7.2 Radioactive Materials - Financial Assurance and Record keeping for Decommissioning.**

Response from Applicant:

Item 9.11 Termination Of Activities (Check box)
☐ We will notify VDH, in writing, within 60 days of the decision to permanently cease radioactive material use. **(12VAC5-481-500 D 1)**

Item 10: License Fees

On VDH form, 'Application for a Radioactive Material License Authorizing the Use of Sealed Sources', enter the fee category and the amount. Enclose fee with the application.

Response from Applicant:

Item 10 License Fees (Refer to **12VAC5-490.**)	
Category:	License Fee Enclosed ☐ Yes ☐ No Amount Enclosed $ _____

Item 11: Certification

Individuals acting in a private capacity are required to sign and date VDH form, 'Application for a Radioactive Material License Authorizing the Use of Sealed Sources'. Otherwise, senior representatives of the corporation or legal entity filing the application should sign and date VDH form, 'Application for a Radioactive Material License Authorizing the Use of Sealed Sources'. **Representatives signing an application must be authorized to make binding commitments and sign official documents on behalf of the applicant.** The agency will return all unsigned applications for proper signature.

Note:

- It is a violation of **12VAC5-481-30** to make a willful false statement or representation on applications or correspondence.
- When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

Response from Applicant:

Item 11 I hereby certify that this application was prepared in conformance with **12VAC5-481, '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 A:

VDH Form,
'Application for a Radioactive Material License Authorizing the Use of Sealed Sources'

VIRGINIA DEPARTMENT OF HEALTH
Radioactive Materials Program
109 Governor Street, Room 730
Richmond, VA 23219
(804) 864-8150

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE AUTHORIZING THE USE OF SEALED SOURCES

The 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. Refer to VAREG "Guidance for The Use of Sealed Sources" for additional information. Use supplementary sheets if necessary. Retain a copy and submit the original of the entire application to: Virginia Department of Health, Radioactive Materials Program, 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 this application**
Applicant's Telephone Number (Include Area Code) ( ) -	**Contact's Telephone Number** (Include Area Code) ( ) -

LOCATION OF RADIOACTIVE MATERIAL

Item 4 List all address(es) where radioactive material(s) will be used or possessed. (Attach additional pages if necessary)

	Address (Do not use Post Office box)	**Telephone Number** (Include area code)
☐ Used ☐ Stored ☐ Used and Stored		( ) -
☐ Used ☐ Stored ☐ Used and Stored		( ) -
☐ Used ☐ Stored ☐ Used and Stored		( ) -

Are sealed sources used at temporary jobsites?: ☐ Yes ☐ No

RADIATION SAFETY OFFICER

Item 5 Radiation Safety Officer (RSO) (Check both boxes)

☐ 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.

NAME:

TELEPHONE NUMBER: ( ) -
(Include area code)

AUTHORIZED USERS

Item 6 Authorized Users (check all that apply)

☐ 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.

NOTE: If requesting authorization to perform non-routine maintenance, submit outline of the instruction and training for individuals performing non-routine maintenance.

RADIOACTIVE MATERIAL

Item 7 Radioactive Material (Attach additional pages if necessary)

Element and mass number

Source manufacturer and model number	Maximum activity per source
Device manufacturer and model number	Intended use

FACILITIES AND EQUIPMENT

Item 8 Facilities And Equipment (Check box and attach diagram.)

☐ Diagrams of radioactive material storage area(s) are attached.

RADIATION SAFETY PROGRAM

Item 9 Radiation Safety Program

Item 9.1 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 9.2 Radiation Monitoring Instruments (Check all that apply)

☐ We will have access to a survey meter that meets the Criteria in the section titled "Radiation Monitoring Instruments" in VAREG "Guidance for Uses of Sealed Sources". (Description attached)

OR

☐ We will possess a survey meter that meets the Criteria in the section titled "Radiation Monitoring Instruments" in VAREG "Guidance for Uses of Sealed Sources."

AND ONE OF THE FOLLOWING

☐ Each survey meter will be calibrated by an organization licensed by VDH, the NRC or another Agreement State to perform survey meter calibrations.

OR

☐ We will implement the model survey meter calibration program published in Appendix E in VAREG "Guidance for Uses of Sealed Sources."

OR

☐ We will submit alternative calibration procedures for agency review. (Procedures are attached)

Item 9.3 Material Receipt And Accountability (Check one box)

will conduct physical inventories at intervals not to exceed 6 months, to account for all sealed sources and devices received and 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. (Procedures are attached)

Item 9.4 Occupational Dosimetry (Check one)

☐ We will maintain, for inspection by the agency, 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.

Item 9.5 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 9.6 Operating And Emergency Procedures (Check box)

☐ Operating and emergency procedures will be developed, implemented, and maintained, and will meet criteria in the section titled 'Operating and Emergency Procedures' in VAREG " Guidance for Uses of Sealed Sources." (Procedures are attached)

Item 9.7 Leak Tests (Check one box)

☐ 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 supplier's instructions.

List name and license number of organization authorized to perform or analyze leak tests (Specify whether VDH, NRC, or another 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 another Agreement State.

OR

☐ We will perform leak testing and sample analysis and will follow the procedures in Appendix J of VAREG "Guidance for Uses of Sealed Sources." (Procedures are attached)

OR

☐ We will submit alternative procedures. (Procedures are attached)

Item 9.8 Maintenance and Repair (Check one box)

☐ We will send the device to the manufacturer or other person authorized by VDH, the NRC or another Agreement State to perform maintenance or repair operations.

OR

☐ We will implement and maintain procedures for maintenance of devices containing sealed sources according to each manufacturer's recommendations and instructions.

OR

☐ We will develop, implement and maintain procedures for maintenance of devices containing sealed sources. (Procedures are attached)

OR

☐ We will only possess sealed sources not in devices. No maintenance or repair is required.

Item 9.9 Transportation

No response is needed during the license process; this issue will be reviewed during inspection.

Item 9.10 Waste Management (Check box)

☐ We will transfer the sealed source or device containing the sealed source to the manufacturer or a specifically licensed recipient for disposal.

Item 9.11 Termination Of Activities (Check box)

☐ We will notify the agency, in writing, within 60 days of the decision to permanently cease radioactive material use **(12 VAC 5-481-510)**.

SPECIFIC LICENSE FEE

Item 10 License Fees (12VAC5-490).

Category:	License Fee Enclosed ☐ Yes ☐ No Amount Enclosed $

CERTIFICATION (To be signed by an individual authorized to make binding commitments on behalf of the applicant.)

Item 11

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 Materials'

Virginia Department of Health
Radioactive Materials Program
109 Governor St., Room 730
Richmond, VA 23219
(804) 864-8150

CERTIFICATE OF DISPOSITION OF MATERIALS

Completion of this form is required to complete termination of a Radioactive Material License as outlined in **12VAC5-481-510.** Failure to provide information will result in this request for termination of a specific license not being processed.

Instructions – Complete all items. Retain one copy and submit original to Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219.

CONTACT INFORMATION

Item 1 Name and Mailing Address of Applicant:	**Item 2 Virginia Radioactive Material License Number**
	Item 3 Contact Person – Name
	Contact Person - Telephone Number (Include area code) ( ) - x

TERMINATION AND DISPOSITION INFORMATION

The following information is provided in accordance with **12VAC5-481-510.** (Check all that apply)

☐ **Item 4** All use of radioactive material authorized under the above referenced license has been terminated.

☐ **Item 5** Radioactive contamination has been removed to the levels outlined in **12VAC5-481-1161 B.**

☐ **Item 6** All radioactive material previously procured and/or possessed under the authorization granted by the above referenced license has been disposed of as follows. (Check all that apply)

☐ Transferred to: Name Address

Who is (are) authorized to possess such material under Licensed Number:

Issued by (Licensing Agency):

☐ Decayed, surveyed and disposed of as non-radioactive waste.

☐ No radioactive material has ever been procured and/or possessed by the licensee under the authorization granted by the above referenced license.

☐ Other (Attach additional pages)

☐ **Item 7** Attached are radiation surveys or equivalent as specified in **12VAC5-481-510 L.** Specify the survey instrument(s) used and certify that each instrument is properly calibrated as required in **12VAC5-481-510 K.**

☐ **Item 8** Records required to be maintained for the license termination requested are available at the following location(s):

Name:

Address:

Contact Person Telephone Number: ( ) - x

Additional remarks (Attach additional pages if necessary.)

CERTIFICATION (To be completed by an individual authorized to make binding commitments on behalf of the applicant.)

Item 10.

The undersigned, on behalf of the licensee, hereby certifies that licensable quantities of radioactive material under the jurisdiction of the Virginia Department of Health are not possessed by the licensee. It is therefore requested that the above referenced radioactive material license be terminated.

SIGNATURE - Applicant or Authorized Individual	**Date signed**

Print Name and Title of Above Signatroy

Appendix C:

Information Needed for Transfer of Control Application

Information Needed for Transfer of Control Application

Control: Control of a license is in the hands of the person or persons who are empowered to decide when and how that license will be used. That control is to be found in the person or persons who, because of ownership or authority explicitly delegated by the owners, possess the power to determine corporate policy, and thus the direction of the activities under the license.

Transferee: A transferee is an entity that proposes to purchase or otherwise gain control of a VDH licensed operation.

Transferor: A transferor is a VDH licensee selling or otherwise giving up control of a licensed operation.

Licensees must provide full information and obtain VDH's **prior written consent** before transferring control of the license. Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

1. Provide a complete description of the transaction (transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact who the agency may contact if more information is needed.

2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.

3. Describe any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.

4. Describe the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.

5. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to VDH, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.

6. Confirm that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

Appendix D:

Criteria for Acceptable Training and Experience for Authorized Users

Criteria for Acceptable Training and Experience for Authorized Users Classroom Training

Classroom training may be in the form of lecture, videotape, or self-study that emphasize practical subject matter important to the safe handling of licensed materials. Duration and technical level of training should be commensurate with the expected hazards encountered during routine and emergency conditions.

Frequency of Training

- Before assuming duties with, or in the vicinity of, radioactive materials;
- Whenever there is a significant change in duties, regulations, or the terms and conditions of the license;
- Annually for refresher training.

Suggested Radiation Safety Topics

- Fundamentals of Radiation Safety:
  - Characteristics of radiation;
  - Units of radiation dose and quantity of radioactivity;
  - Hazards of exposure to radiation;
  - Levels of radiation from licensed material;
  - Methods of controlling radiation dose (time, distance, and shielding);
  - ALARA concept.
- Radiation Detection Instruments:
  - Operation;
  - Calibration;
  - Limitations of radiation survey instruments;
  - Radiation survey techniques for measuring radiation field;
  - Radiation survey techniques for measuring removable/fixed contamination;
  - Handling and proper use of personnel monitoring equipment.
- Radiation Protection Equipment and Use:
  - Proper use of protective equipment;
  - Decontamination of contaminated protection equipment.
- **12VAC5-481, 'Virginia Radiation Protection Regulations'**
- Licensee's operating and emergency procedures.
- Case histories relevant to operations.
- Course Examination (Didactic):
  - Successful completion of closed-book written/oral examination depending on the complexity and hazards of authorized activities;
  - Review of incorrect answers with student.
- On-the Job Training and Examination (Practical):
  - On-the-job training done under the supervision of a qualified individual (AU, RSO, or manufacturer's representative authorized by VDH, NRC, or another Agreement State) that includes supervised hands-on experience performing the task authorized on the license that are commensurate with the expected hazards during routine and emergency conditions;
  - Practical examination consisting of an assessment by the RSO to ensure that each proposed AU is qualified to work independently and that each

individual is knowledgeable of the radiation safety aspects of licensed activities. This may be demonstrated by observing the proposed AU perform licensed activities.

- Discussion and/or drill on emergency procedures.
- Retraining on areas found to be deficient in both the practical and didactic areas.

Classroom Course Instructor Qualifications

The person conducting the training should be a qualified individual (e.g., a person who meets the qualifications for RSO or authorized user (AU) on the license and is familiar with the licensee's program). Instructors who provide classroom training to individuals in the principles of radiation and radiation safety should have knowledge and understanding of these principles beyond those obtainable in a course similar to the one given to prospective AUs. Individuals who provide instruction in the hands-on use of licensed materials should have training and experience that would qualify them to be AUs, or should possess a thorough understanding of the licensee operations.

Appendix E:

Radiation Monitoring Instrument Specifications and Survey Instrument Calibration Program

Radiation Monitoring Instrument Specifications and Survey Instrument Calibration Program

The specifications in **Table 3** will help choose the proper radiation detection equipment for monitoring the radiological conditions at facilities or job sites.

Table 3. Typical Survey Instruments[1]

Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	**Radiation**	**Energy Range**	**Efficiency**
Exposure Rate Maters	Gamma, X-Ray	FR-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
Plasitic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate
Stationary Instruments Used to Measure Wipe, Bioassay and Effluent Samples			
Detectors	**Radiation**	**Energy Range**	**Efficiency**
LSC*	Alpha	All energies	High
	Beta	All energies	High
	Gamma		Moderate
Gamma Counter (NaI)*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

[1] Table from The Health Physics & Radiological Health Handbook, Revised Edition, Edited by Bernard Shleien, 1992 (except for * items).

Instrument Calibration Program

Training

Before allowing an individual to perform survey instrument calibrations, the RSO will ensure that he or she has sufficient training and experience to perform independent survey instrument calibrations.

Classroom training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection;
- Radioactivity measurements, monitoring techniques, and using instruments;
- Mathematics and calculations basic to using and measuring radioactivity;
- Biological effects of radiation.

Appropriate on-the-job training consists of the following:

- Observing authorized personnel performing survey instrument calibration;
- Conducting survey meter calibrations under the supervision and in the physical presence of an individual authorized to perform calibrations.

Facilities and Equipment 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 to be within $\pm$ 5% accuracy by the National Institutes of Standards and Technology (NIST);
- Approximately the same energy and type of radiation as the environment in which the calibrated device will be employed or develop energy curves to compensate for differing energies;
- For dose rate and exposure rate instruments, the source should be strong enough to give an exposure rate of at least about 7.7 X 10^{-6} coulombs/kilogram/hour (30 mR/hr) at 100 cm [e.g., 3.1 GBqs (85 mCi) of cesium-137 or 7.8 X 102 MBqs (21 mCi) of cobalt-60].

The three kinds of scales frequently used on dose or dose rate survey meters are calibrated as follows:

- Linear readout instruments with a single calibration control for all scales should 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 should be adjusted on each scale. After adjustment, the response of the instrument should be checked at approximately 20% and 80%

of full scale. The instrument's readings should be within ± 15% of the conventionally true values for the lower point and ±10% for the upper point.

- Logarithmic readout instruments, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. The instrument should be adjusted for each scale according to site specifications or the manufacturer's specifications. After adjustment, calibration should be checked at a minimum of one point on each decade. Instrument readings should have a maximum deviation from the conventionally true value of no more the 10% of the full decade value.
- Meters with a digital display device shall be calibrated the same as meters with a linear scale.
- Readings about 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.
- The inverse square and radioactive decay laws should be used to correct changes in exposure rate due to changes in distance or source decay.

Surface Contamination Measurement Instruments

- A survey meter's efficiency must be determined by using radiation sources with similar energies and types of radiation that the survey instrument will be used to measure or develop energy curves to compensate for differing energies.
- If each scale has a calibration potentiometer, the reading should be adjusted to read the conventionally true value at approximately 80% of full scale and the reading at approximately 20% of full scale should be observed. If only one calibration potentiometer is available, the reading should be adjusted at mid-scale on one of the scales, and readings on the other scales should be observed. Readings should 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 to be within ±5% accuracy by the National Institutes of Standards and Technology (NIST).
- Approximately the same energy and type of radiation as the samples that the calibrated device will be used to measure.

Calibration

- Calibration of survey instruments used in assessing dose or exposure rates must be conducted at 6 to 12 month intervals or after instrument servicing.
- Calibration must produce readings within ±20 percent 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 date 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 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 the radiation flux field and a specified surface of the instrument;
- For detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure;
- The exposure rate or count rate from a check source, if used;
- The name of the person who performed the calibration and 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 the calibration and the next calibration due date;
- The apparent exposure rate or count rate from the check source, if used.

References:

1. NRC Draft Regulatory Guide FC 413-4, "*Guide for the Preparation of Applications for Licenses for the Use of Radioactive Material in Calibrating Radiation Survey and Monitoring Instruments*", dated June 1985.
2. "*The Health Physics & Radiological Health Handbook, Revised Edition*", edited by Bernard Shleien, dated 1992.
3. 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.

Appendix F:

Audit Checklist

NOTE: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit.

Licensee's name:_____ License No._____

Auditor: _____Date of Audit _____Telephone No._____

_____
(Signature)

1. AUDIT HISTORY

a. Last audit of this location conducted on (date) _____

b. Are audits conducted yearly? **(12VAC5-481-630)**

c. Are records of previous audits maintained? **(12VAC5-481-990)**

d. Were any deficiencies identified during last two audits or two years, whichever is longer?

If yes, were corrective actions taken? (Look for repeated deficiencies).

2. ORGANIZATION AND SCOPE OF PROGRAM

a. If the mailing address or places of use changed, was the license amended?

b. If ownership changed was prior VDH consent obtained?

c. If bankruptcy was filed was VDH notified immediately?

d. If the RSO was changed, was license amended? Does new RSO meet VDH training requirements?

e. If the designated contact person changed, was the agency notified?

f. Does the license authorize all of the VDH regulated radionuclides?

g. Are the sealed sources and devices being used as described in the Sealed Source and Device Registration (SSDR) Certificate or Sheet? Are copies of SSDR Certificates available? Are manufacturers' manuals for operation and maintenance available?

h. Are the actual uses of sealed sources consistent with the authorized uses listed on the license?

i. Is RSO fulfilling his/her duties?

3. TRAINING AND INSTRUCTIONS TO WORKERS

a. Are all workers who are likely to exceed 100 mrem (1 mSv) in a year given training annually per **12VAC5-481-2270**?

b. Did each authorized user receive training as committed to in the license application?

c. Are training records maintained for each authorized user?

d. Did interviews with authorized users reveal that they know the operating and emergency procedures?

e. Did this audit include observations of authorized users using the sealed sources or devices (i.e., routine use, transporting, storage)?

If yes, was safe handling and security demonstrated during transportation, use and storage of the sealed source?

f. HAZMAT training provided as required? **[49 CFR 172.700, 49 CFR 172.701,CFR 172.702, 49 CFR 172.703, 49 CFR 172.704]**

4. RADIATION SURVEY INSTRUMENTS

a. Does the licensee possess or have access to a survey meter? **(L/C)**

Is the survey meter calibrated at least annually? **(12VAC5-481-750)**
Are calibration records maintained **(12VAC5-481-1000)**?

5. SEALED SOURCE INVENTORY

a. Are records kept showing the receipt of each sealed source? **(12VAC5-481-100, 12VAC5-481-571)**

b. Are all sealed sources physically inventoried every 6 months?

c. Are records of inventory results maintained?

6. PERSONNEL RADIATION PROTECTION

a. Are ALARA considerations incorporated into the radiation protection program? **(12VAC5-481-630)**

b. Is documentation kept showing that unmonitored authorized users receive <10% of limit?

c. Did unmonitored users' activities change during the year which could put them over 10% of limit?

If yes, was a new evaluation performed?

d. Is external dosimetry required and is dosimetry provided to users?

1) Is the dosimetry supplier NVLAP approved? **(12VAC5-481-750)**

2) Are the dosimeters exchanged at vendors recommended frequency?

3) Are dosimetry reports reviewed by the RSO when they are received?

4) Are the records VDH Forms or equivalent? **(12VAC5-481-1080)**

VDH form "Occupational Exposure Record for a Monitoring Period" completed?

5) If a worker declared her pregnancy, did licensee comply with **12VAC5-481-710**?

Are records kept of embryo/fetus dose per **12VAC5-481-1040**?

6) Are annual dosimetry reports provided to monitored individuals? **(12VAC5-481-2280)**

e. Are records of exposures, surveys, monitoring, and evaluations maintained? **(12VAC5-481-1000, 12VAC5-481-1040)**

7. PUBLIC DOSE AND SECURITY

a. Are sealed sources stored in a manner to keep doses below 100 mrem (1 mSv) in a year and 2 mrem in any one hour? **(12VAC5-481-720)**

b. Has a survey or evaluation been performed per **12VAC5-481-730**? Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?

c. Are sealed sources being stored in a manner that would prevent

unauthorized use or removal? **(12VAC5-481-840)**

d. Are records of surveys or evaluations maintained? **(12VAC5-481-1000, 12VAC5-481-1050)**

8. OPERATING AND EMERGENCY PROCEDURES

Are operating and emergency procedures available?

Are they being followed?

Are they current?

9. LEAK TESTS

a. Was each sealed source leak tested every 6 months or at other approved intervals? **(12VAC5-481-740)**

b. Was the leak test performed as described in license application?

c. Are records of results with appropriate information retained for three years? **(12VAC5-481-1010)**

d. Are any sources found leaking and if yes, was VDH notified?

10 MAINTENANCE OF SEALED SOURCE DEVICES

Is any maintenance of the sealed source device performed?

If yes, was it performed according to license requirements (e.g., scope of work, authorized individuals performing the work, procedures used, dosimetry worn, survey instrument there, compliance with **12VAC5-481-640** limits)?

11 TRANSPORTATION OF SEALED SOURCES OR DEVICES

a. DOT-7A or other authorized packages used? **(49 CFR 173.415, 49 CFR 173.416(b))**

b. Package performance test records on file?

c. Special form sources documentation? **(49 CFR 173.476(a))**

d. Package has 2 labels (ex. Yellow-II) with TI, Nuclide, Activity, and Hazard Class? **(49 CFR 172.403, 49 CFR 173.441)**

e. Package properly marked? **(49 CFR 172.301, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324)**

f. Package closed and sealed during transport? **(49 CFR 173.475(f))**

g. Shipping papers prepared and used? **(49 CFR 172.200(a))**

h. Shipping papers contain proper entries? {Shipping name, Hazard Class, Identification Number (UN Number), Total 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, Cargo Aircraft Only (if applicable)} **(49 CFR 172.200, 49 CFR 172.201, 49 CFR 172.202, 49 CFR 172.203, 49 CFR 172.204, 49 CFR 172.604)**

i. Shipping papers within drivers reach and readily accessible during transport? **(49 CFR 177. 817(e))**

j. Secured against movement? **(49 CFR 177. 834)**

k. Placarded on vehicle, if needed? **(49 CFR 172.504)**

l. Proper overpacks, if used? **(49 CFR 173.25)**

m. Any incidents reported to DOT? **(49 CFR 171.15, 16)**

12 AUDITOR'S SURVEY MEASUREMENTS (IF MADE)

a. Were radiation surveys performed?

If yes, describe the type, location, and results measurements.

b. Did any radiation level exceed regulatory limits?

If yes, were corrective actions taken?

13 NOTIFICATION AND REPORTS

a. Was any radioactive material lost or stolen and reports made to VDH? **(12VAC5-481-1090)**

b. Did any reportable incidents occur? Are reports made? **(12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1150)**

c. Did any overexposures and high radiation levels occur? Reported? **(12VAC5-481-1100, 12VAC5-481-1110)**

d. If any events (as described in items a through c above) did occur, what were the root causes? Are corrective actions appropriate?

e. Is the licensee's management/RSO/authorized individuals aware of how to contact VDH for radiological incidents?
Note: VDH office hour number (804) 864-8150 or 24 hour emergency number (804) 674-2400 or (800) 468-8892.

14 POSTING AND LABELING

a. Is VDH form, "Notice to Employees" posted? **(12VAC5-481-2260)**

b. Are **12VAC5-481, 'Virginia Radiation Protection Regulations',** and license documents posted or a notice posted? **(12VAC5-481-2260)**

c. Were any notice of violation, forfeiture assessment, or order issued under §32.1-229 or §32.1-234, or **12VAC5-481, 'Virginia Radiation Protection Regulations'** and any response from the licensee is posted until removal is authorized by VDH?
(12VAC5-481-2260)

d. Are emergency procedures posted?

e. Are storage/use areas posted, if required? **(12VAC5-481-860)**

f. Is the sealed source/device properly labeled? **(12VAC5-481-880)**

15. RECORD KEEPING FOR DECOMMISSIONING

a. Are records kept of information important to decommissioning? **(12VAC5-481-450 C)**

b. Do records include all information as outlined in **12VAC5-481-450 C**?

16. INFORMATION NOTICES

a. Are Information Notices received?

b. Was appropriate action taken in response?

17. LICENSE CONDITIONS OR ISSUES

Did auditor review license conditions or other issues (e.g., maintenance)?

18. DEFICIENCIES IDENTIFIED IN AUDIT; CORRECTIVE ACTIONS

a. Summarize problems/deficiencies identified during audit.

   If problems/deficiencies were identified in this audit, describe the corrective actions planned or taken.

b. Are corrective actions planned or taken at ALL licensed locations (not just location audited)?

c. Provide any other recommendations for improvement.

19. EVALUATION OF OTHER FACTORS

a. Is senior licensee management appropriately involved with the radiation protection program and RSO oversight?

b. Does the RSO have sufficient time to perform his/her radiation safety duties?

c. Does the licensee have sufficient staff to support the radiation protection program?

Appendix G:

Information Needed to Support a Sealed Source Licensee's Request to Perform Maintenance and Repair

Applicants wishing to perform maintenance must use personnel with special training and follow appropriate procedures consistent with the manufacturer's instructions and recommendations that address radiation safety concerns (e.g., use of radiation survey meter, shielded container for the source, personnel dosimetry). Applicants should include the following information:

- Describe the type of work that necessitates performing maintenance on the sealed source device. The principal reason for obtaining this information is to assist the agency in the evaluation of the qualifications of individuals who will conduct the work and the radiation safety procedures they will follow.
- Identify who will perform maintenance, their training and experience, and why they are competent to perform maintenance.
- Submit procedures for the safe handling of the radioactive source while the maintenance is being performed. These procedures should ensure the following:
  - doses to personnel and members of the public are within regulatory limits and ALARA (e.g., use of shielded containers or shielding);
  - the sealed source is secured against unauthorized removal access or under constant surveillance;
  - appropriate labels and signs are used; and
  - manufacturer's instructions and recommendations will be followed.
- Confirm that individuals performing maintenance on the sealed source device will always wear appropriate monitoring devices or that an evaluation will be available to demonstrate that these individuals are not likely to receive, in one year, more than 10 percent of the applicable dose limits. The dose limits are in **Table 2**.
- Verify possession of at least one survey instrument meeting the following criteria:
  - Be capable of detecting gamma radiation;
  - Be capable of measuring from 0.01 to 0.5 mSv/hr (1 to 50 mrem/hr);
  - Be calibrated at least annually with radionuclide point sources emitting radiation of the type and energy of the sealed sources;
  - Be calibrated on at least 2 points located at approximately 1/3 and 2/3 of each scale; readings within ±20% are acceptable;
  - Be calibrated by a person specifically licensed by VDH, NRC, or another Agreement State to calibrate radiation detection instruments; and
  - Be checked for functionality prior to use (e.g., with the gauge or a check source).

  Note: Records of instrument calibration must be maintained for 3 years after the record is made **(12VAC5-481-1000)**.
- Describe steps to be taken to ensure that radiation levels in areas where maintenance will take place do not exceed **12VAC5-481-720** limits. For example, applicants can do the following:
  - Commit to performing surveys with a survey instrument (as described above);
  - Specify where and when surveys will be conducted during maintenance; and
  - Commit to maintaining, for 3 years from the date of the survey, records of the survey (e.g., who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements) as required by **12VAC5-481-1000**.

Appendix H:

Operating and Emergency Procedures

Operating Procedures

- If personnel dosimetry is provided:
  - Always wear your assigned TLD, OSL, or film badge when using or around the sealed source;
  - Never wear another person's TLD, OSL, or film badge; and
  - Never store your TLD, OSL, or film badge near the sealed source.
- Use the sealed source according to the manufacturer's instructions and recommendations.
- Do not touch the unshielded sealed source with your fingers, hands, or any part of your body.
- Do not place hands, fingers, feet, or other body parts in the radiation field from an unshielded sealed source.
- Perform routine cleaning and maintenance according to the manufacturer's instructions and recommendations.
- When not in use, place the sealed source in a secured location.
- After making changes affecting the sealed source storage area (e.g., changing the location of sealed sources within the storage area, removing shielding, adding sealed sources, changing the occupancy of adjacent areas, moving the storage area to a new location), reevaluate compliance with public dose limits and ensure proper security of the sealed sources.

Emergency Procedures for Sealed Sources

If the sealed source is lost, damaged, or stolen or if any other emergency or unusual incident occurs:

- Immediately secure the area and keep people a safe distance away from the sealed source until the situation is assessed and radiation levels are known. However, perform first aid for any injured individuals and remove them from the area only when medically safe to do so.
- Authorized users and other potentially contaminated individuals should not leave the scene until emergency assistance arrives.
- Notify the persons, in order listed, of the situation.
- Follow the directions provided by the person contacted.

NAME*	WORK PHONE NUMBER*	HOME PHONE NUMBER*

* Fill in with (and update, as needed) the names and telephone numbers of appropriate personnel (e.g., the RSO or other knowledgeable licensee staff, licensee's consultant, sealed source manufacturer) to be contacted in case of emergency.

Upon notification of an emergency or incident, the contacted person (RSO or licensee management) should:

- Arrange for a radiation survey to be conducted as soon as possible by a knowledgeable person using appropriate radiation detection instrumentation. This person could be a licensee employee using a survey meter located at the jobsite or a consultant. To accurately assess the radiation danger, it is essential that the person performing the survey be competent in the use of the survey meter.
- Make necessary notifications to local authorities as well as VDH. Even if not required to do so, you may report any incident to VDH by calling **(804) 864-8150 during office hours or (804) 674-2400 or (800) 468-8892 after hours**. VDH notification is required when sealed sources are lost or stolen, when sealed sources are damaged or involved in incidents that result in doses in excess of **12VAC5-481-640** and **12VAC5-481-720** limits.
- Reports to VDH must be made within the reporting timeframes specified by **12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110,** and **12VAC5-481-1150**.

Appendix I:

Dosimetry-related Guidance

Part 1:
Worksheet for Determining if Personnel Dosimetry is Required for Sealed Source Users

Worksheet for Determining if Personnel Dosimetry is Required for Sealed Source Users

Instructions: To meet the requirement of **12VAC5-481-760** complete **Steps 1** through **6** and sign and date the evaluation on the line provided.

Disclaimer: If there is a change in workload or if a new sealed source is acquired, a new evaluation will need to be performed.

Step 1.

Determine the radiation level in one of the following ways. Record the results below.

- Obtain from the manufacturer's specifications: the radiation level approximately 30 centimeters from the sealed source, or
- Measure the radiation level with a calibrated survey meter.
  - When making the radiation measurement, place the survey instrument approximately 30 centimeters from the sealed source while following good radiation safety practices.

_____ mrem per hour

Step 2.

Record the average number of minutes per week that the sealed source is used.

_____ minutes per week

Step 3.

Divide the minutes per week (**Step 2.**) by 60 to determine hours per week and record below.

_____ minutes per week (**Step 2.**) / 60

= _____ hours per week

Step 4.

Multiply the hours per week (**Step 3.**) by 52 weeks to equal hours per year and record below.

_____ hours per week (**Step 3.**) X 52 weeks

= _____ hours per year

Step 5.

Multiply hours per year (**Step 4.**) by mrem per hour (**Step 1.**) to equal mrem received per year and record below.

_____hours per year (**Step 4.**) X _____mrem per hour (**Step 1.**)

= _____ mrem per year

Step 6.

Is the # of mrem per year (**Step 5.**) greater than 500? ☐ Yes ☐ No

- If yes provide dosimetry as required by **12VAC5-481-760**
- If no, proceed to **Step 7.**

Step 7.

Is the # of mrem per year (**Step 5.**) greater than 100? ☐ Yes ☐ No

- If yes, and you have an employee that is a declared pregnant worker, as defined by **12VAC5-481-10,** provide dosimetry to that individual. In addition, provide annual radiation safety training as required by **12VAC5-481-2270** to all employees that use the sealed source.
- If no, you are not required under **12VAC5-481-640** and **12VAC5-481-760** to provide dosimetry to your employees.

_____ _____

Signature of Person Performing the Evaluation | Date

Part 2:
Guidance for Demonstrating that Individual Members of the Public will not Receive Doses Exceeding the Allowable Limit

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 mSv (100 mrem) in one calendar year resulting from the licensee's possession and/or use of licensed materials.

Members of the public include persons who live, work, or may be near locations where sealed sources are used or stored. (For storage of sealed sources in personal residences, occupants are considered members of the public.) Employees whose assigned duties do not include the use of licensed materials but who work in the vicinity where sealed sources are used or stored are also considered members of the public.

- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.

Typical unrestricted areas may include offices, shops, laboratories, areas outside buildings, property, and non-radioactive equipment storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials. However, the licensee may control access to these areas for other reasons such as security.

Licensees must show compliance with both portions of the rule. Calculations or a combination of calculations and measurements (e.g., using an environmental TLD) are often used to prove compliance.

Calculation Method

The calculation method takes a tiered approach, going through a three-part process starting with a worst case situation and moving toward more realistic situations. It makes the following simplifications: (1) each sealed source is a point source, (2) typical radiation levels encountered when the source is in the shielded position are taken from either the Sealed Source Device Registration Sheet or the manufacturer's literature, and (3) no credit is taken for any shielding found between the sealed sources and the unrestricted areas. Part 1 of the calculation method is simple but conservative. It assumes that an affected member of the public is present 24 hours a day and uses only the 'inverse square law' to determine if the distance between the sealed source and the affected member of the public is sufficient to show compliance with the public dose limits. Part 2 considers not only distance, but also the time that the affected member of the public is actually in the area under consideration. Part 3 considers distance and the portion of time that both the sealed source and the affected member of the public are present. Using this approach, licensees make only those calculations that are needed to demonstrate compliance. In many cases licensees will need to use the calculation method through Part 1 or Part 2. The results of these calculations typically result in higher radiation levels than would exist at typical facilities, but provide a method for estimating conservative doses which could be received.

Example 1

To better understand the calculation method, we will look at a sealed source licensee. Yesterday, the company's president noted that the new sealed source storage area is very close to his secretary's desk and he asked Joe, the RSO, to determine if the company is complying with **12VAC5-481-720.**

The secretary's desk is near the wall separating the reception area from the designated, locked sealed source storage area, where the company is storing three sealed sources. Joe measures the distances from each sealed source to the wall and looks up in the manufacturer's literature the

radiation levels individuals would encounter for each sealed source. **Figure 1** is Joe's sketch of the areas in question and **Table 4** summarizes the information Joe has on each sealed source.

A Bird's Eye View of Office and Gauge Storage Area

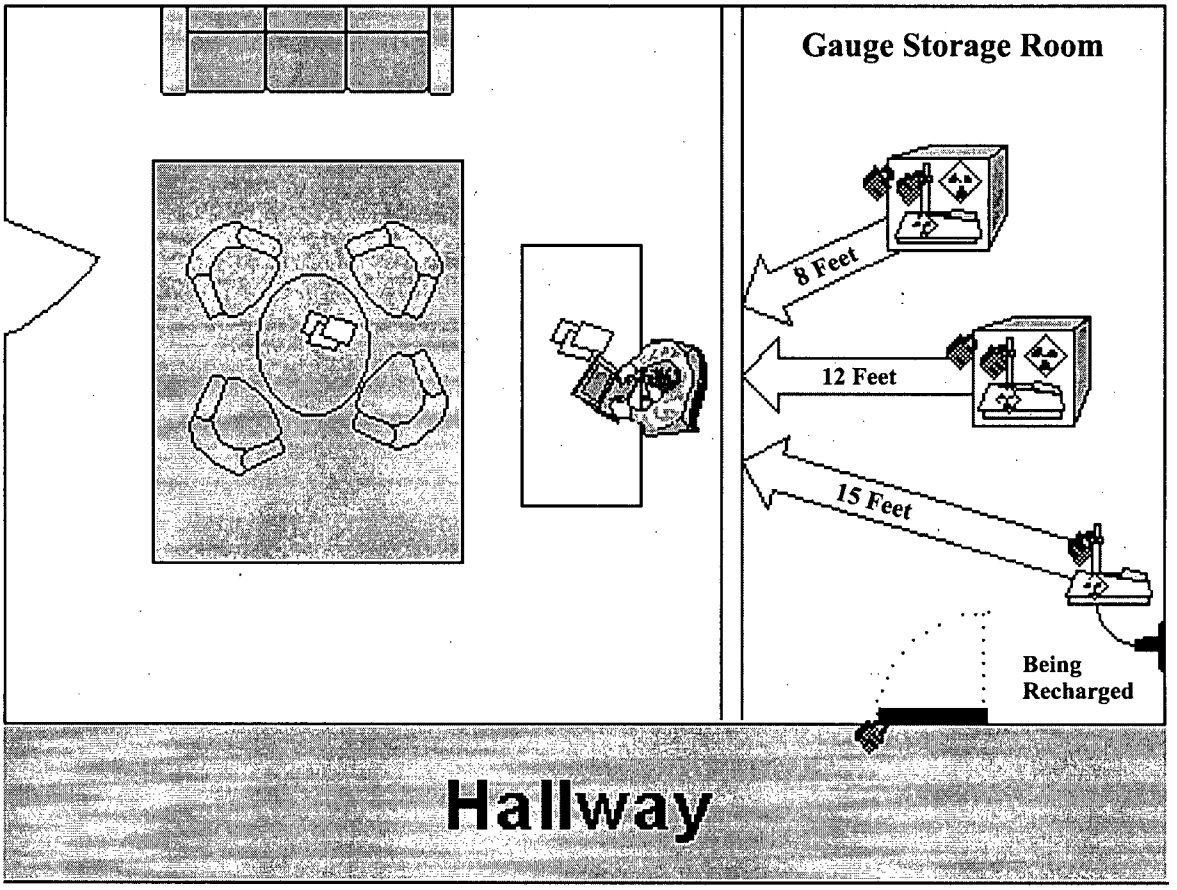


Figure 1. Diagram of Office and Sealed Source Storage Area.

Table 4. Information Known about Each Sealed Source

DESCRIPTION OF KNOWN INFORMATION	GAUGE 1	GAUGE 2	GAUGE 3
How sealed source is stored	Sealed source in storage container	Sealed source in storage container	Sealed source out of storage container
Dose rate in mrem/hr encountered at specified distance from the sealed source (from manufacturer's literature)	2 mrem/hr at 1 ft	8 mrem/hr at 1 ft	2 mrem/hr at 3 ft
Distance in ft to secretary's chair	8 ft	12 ft	15 ft

Example 1: Part 1

Joe's first thought is that the distance between the sealed sources and the secretary's chair may be sufficient to show compliance with the rule in **12VAC5-481-720**. So, taking a 'worst case' approach, he assumes: 1) the sealed sources are constantly present (i.e., 24 hr/d), 2) all three sealed sources remain in storage with no other use, and 3) the secretary is constantly sitting in the desk chair (i.e., 24 hr/d).

Joe proceeds to calculate the dose she might receive hourly and yearly from each sealed source as shown in **Tables 5**, **6**, and **7** below.

Table 5. Calculation Method, Part 1---Hourly and Annual Dose Received from Sealed Source 1

		Sealed Source 1	
Step No.	**Description**	**Input Data**	**Results**
1	Dose received in an hour at known distance from the sealed source (e.g., from manufacturer's data), in mrem/hr	2	2
2	Square of the distance (ft) at which the Step 1 rate was measured, in ft^2	$(1)^2$	1
3	Square of the distance (ft) from the sealed source to the secretary's desk in an unrestricted area, in ft^2	$(8)^2$	64
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	2 x 1 =2	
5	Divide the result of Step 4 by the result of Step 3 to calculate the dose received by an individual at the secretary's desk, **HOURLY DOSE RECEIVED FROM SEALED SOURCE 1**, in mrem in an hour.	2/64 = **0.031**	
6	Multiply the result of Step 5 by 24 hr/d x 365 d/yr = **MAXIMUM ANNUAL DOSE RECEIVED FROM SEALED SOURCE 1**, in mrem in a year.	0.031 x 24 x 365 = 0.031 x 8760 = **272**	

Table 6. Calculation Method, Part 1---Hourly and Annual Dose Received from Sealed Source 2

		Sealed Source 2	
Step No.	**Description**	**Input Data**	**Results**
1	Dose received in an hour at known distance from the sealed source (e.g., from manufacturer's data), in mrem/hr	8	8
2	Square of the distance (ft) at which the Step 1 rate was measured, in ft^2	$(1)^2$	1
3	Square of the distance (ft) from the sealed source to the secretary's desk in an unrestricted area, in ft^2	$(12)^2$	144
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	8 x 1 = 8	
5	Divide the result of Step 4 by the result of Step 3 to calculate dose received in an hour by an individual at the secretary's desk, **HOURLY DOSE RECEIVED FROM SEALED SOURCE 2**, in mrem in an hour	8/144 = **.056**	
6	Multiply the result of Step 5 by 24 hr/d x 365 d/yr = **MAXIMUM ANNUAL DOSE RECEIVED FROM SEALED SOURCE 2**, in mrem in a year	0.056 x 24 x 365 =0.056 x 8760 = **491**	

Table 7. Calculation Method, Part 1---Hourly and Annual Dose Received from Sealed Source 3

		Sealed Source 3	
Step No.	**Description**	**Input Data**	**Results**
1	Dose received in an hour at known distance from the sealed source (e.g., from manufacturer's data), in mrem/hr	2	2
2	Square of the distance (ft) at which the Step 1 rate was measured, in ft^2	$(3)^2$	9
3	Square of the distance (ft) from the sealed source to the secretary's desk in an unrestricted area, in ft^2	$(15)^2$	225
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	2 x 9 =18	
5	Divide the result of Step 4 by the result of Step 3 to calculate dose received by an individual at the secretary's desk, **HOURLY DOSE RECEIVED FROM SEALED SOURCE 3**, in mrem in an hour	18/225 = **0.08**	
6	Multiply the result of Step 5 by 24 hr/d x 365 d/yr = **MAXIMUM ANNUAL DOSE RECEIVED FROM SEALED SOURCE 3**, in mrem in a year	0.08 x 24 x 365 = 0.08 x 8760 = **701**	

To determine the total hourly and total annual dose received, Joe adds the pertinent data from the preceding tables.

Table 8. Calculation Method, Part 1---Total Hourly and Annual Dose Received from Sealed Sources 1, 2, and 3

Step No.	**Description**	**Sealed Source 1**	**Sealed Source 2**	**Sealed Source 3**	**Sum**
7	**TOTAL HOURLY DOSE RECEIVED** from Step 5 of Tables 5, 6, and 7, in mrem in an hour	0.031	0.056	0.08	0.031 + 0.056 + 0.08 = **0.167**
8	**TOTAL ANNUAL DOSE RECEIVED** from Step 6 of Tables 5, 6, and 7, in mrem in a year	272	491	701	272 + 491 + 701 = **1464**

Note: The sum in Step 7 demonstrates compliance with the 2 mrem in any one hour limit. Reevaluate if assumptions change. If the Sum in Step 8 exceeds 100 mrem/yr, proceed to Part 2 of the calculation method.

At this point, Joe is pleased to see that the total dose that an individual could receive in any one hour is only 0.167 mrem, but notes that an individual could receive a dose of 1,464 mrem in a year, much higher than the 100 mrem limit.

Example 1: Part 2

Joe reviews his assumptions and recognizes that the secretary is not at the desk 24 hr/d. He decides to make a realistic estimate of the number of hours the secretary sits in the chair at the desk, keeping his other assumptions constant (i.e., the sealed sources are constantly present (i.e., 24 hr/d), all three sealed sources remain in storage with no other use). He then recalculates the annual dose received.

Table 9. Calculation Method, Part 2--Annual Dose Received from Sealed Sources 1, 2, and 3

Step No.	Description	Results
9	A. Average number of hours per day that individual spends in area of concern (e.g., secretary sits at desk 5 hr/day; the remainder of the day the secretary is away from the desk area copying, filing, etc.)	5
	B. Average number of days per week in area (e.g., secretary is part time and works 3 days/week)	3
	C. Average number of weeks per year in area (e.g., secretary works all year)	52
10	Multiply the results of Step 9.A. by the results of Step 9.B. by the results of Step 9.C. = **AVERAGE NUMBER OF HOURS IN AREA OF CONCERN PER YEAR**	5 x 3 x 52 = **780**
11	Multiply the sum in Step 7 by the results of Step 10 = **ANNUAL DOSE RECEIVED FROM SEALED SOURCES CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN**, in mrem in a year	0.167 x 780 = **130**

Note: If Step 11 exceeds 100 mrem in a year, proceed to Part 3 of the calculation method.

Although Joe is pleased to note that the calculated annual dose received is significantly lower, he realizes it still exceeds the 100 mrem in a year limit.

Example 1, Part 3

Again Joe reviews his assumptions and recognizes that the sealed sources are not always in storage when the secretary is seated at the desk. As he examines the situation, he realizes he must consider each sealed source individually.

Table 10. Calculation Method, Part 3---Summary of Information

INFORMATION ON WHEN SEALED SOURCES ARE PRESENT IN THE STORAGE AREA:

- **SEALED SOURCE 1: an old sealed source located in the storage area continuously (24 hr/d)**
- **SEALED SOURCE 2: a new sealed source located in the storage area continuously (24 hr/d) for 8 months of the year; at job site for the remaining 4 months of the year**
- **SEALED SOURCE 3: a new sealed source located in the storage area overnight; it is used every day all year and returned to the storage location at the end of each day. The sealed source is usually present during the secretary's first and last hours of work each day.**

INFORMATION FROM EXAMPLE 1, PART 2 ON WHEN THE SECRETARY IS SITTING AT THE DESK

- **5 hours per day**
- **3 days per week**
- **52 weeks per year**

Table 11. Calculation Method, Part 3---Annual Dose Received from Sealed Sources 1, 2, and 3

Step No.	Description	Sealed Source 1	Sealed Source 2	Sealed Source 3
12	Average number of **hours per day** sealed source is in storage while secretary is present	**5**	**5**	**2**
13	Average number of **days per week** sealed source is in storage while secretary is present	**3**	**3**	**3**
14	Average number of **weeks per year** sealed source is in storage while secretary is present	**52**	**32**	**52**
15	Multiply the results of Step 12 by the results of Step 13 by the results of Step 14 = **TOTAL HOURS EACH SEALED SOURCE IS STORED PER YEAR WHILE SECRETARY IS PRESENT**	5 x 3 x 52 = **780**	5 x 3 x 32 = **480**	2 x 3 x 52 = **312**
16	Multiply the results of Step 15 by the results of Step 7 = **ANNUAL DOSE RECEIVED FROM EACH SEALED SOURCE**, in mrem in a year	780 x 0.031 = **24**	480 x 0.056 = **27**	312 x 0.08 = **25**
17	Sum the results of Step 16 for each sealed source = **TOTAL ANNUAL DOSE RECEIVED CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN AND TIME SEALED SOURCE IS IN STORAGE**, in mrem in a year	24 + 27 + 25 = **76**		

Note: If the result in Step 17 is greater than 100 mrem/yr, the licensee must take corrective actions.

Joe is pleased that the result in Step 17 shows compliance with the 100 mrem/yr limit. Had the result in Step 17 been higher than 100 mrem/yr, then Joe could have done one or more of the following:

- Consider whether the assumptions used to determine occupancy and the time each sealed source is in storage are accurate, revise the assumptions as needed, and recalculate using the new assumptions;
- Calculate the effect of any shielding located between the sealed source storage area and the secretarial workstation--such calculation is beyond the scope of this Appendix;
- Take corrective action (e.g., move sealed source within storage area, move the storage area, move the secretarial workstation) and perform new calculations to demonstrate compliance; or
- Designate the area outside the storage area as a restricted area and the secretary as an occupationally exposed individual. This would require controlling access to the area for purposes of radiation protection and training the secretary as required by **12VAC5-481-2270**.

Note that in the example, Joe evaluated the unrestricted area outside only one wall of the sealed source storage area. Licensees also need to make similar evaluations for other unrestricted areas and to keep in mind the ALARA principle, taking reasonable steps to keep radiation dose received below regulatory requirements. In addition, licensees need to be alert to changes in

situations (e.g., moving any of the sealed source closer to the secretarial workstation, adding a sealed source to the storage area, changing the secretary to a full-time worker, or changing the estimate of the portion of time spent at the desk) and to perform additional evaluations, as needed.

RECORD KEEPING: 12VAC5-481-1050 requires licensees to maintain records demonstrating compliance with the dose limits for individual members of the public.

Combination Measurement-Calculation Method

This method, which allows the licensee to take credit for shielding between the sealed source and the area in question, begins by measuring radiation levels in the areas, as opposed to using manufacturer-supplied rates at a specified distance from each sealed source. These measurements must be made with calibrated survey meters sufficiently sensitive to measure background levels of radiation. However, licensees must exercise caution when making measurements with currently calibrated radiation survey instruments. A maximum dose of 1 mSv (100 mrem) received by an individual over a period of 2080 hours (i.e., a 'work' year of 40 hr/wk for 52 wk/yr) is equal to less than 0.5 microsievert (0.05 mrem) per hour.

This rate is well below the minimum sensitivity of most commonly available GM survey instruments.

Instruments used to make measurements for calculations must be sufficiently sensitive. An instrument equipped with a scintillation-type detector (e.g., NaI(Tl)) or a micro-R meter used in making very low gamma radiation measurements should be adequate.

Licensees may also choose to use environmental TLD*s* in unrestricted areas next to the sealed source storage area for monitoring. This direct measurement method would provide a definitive measurement of actual radiation levels in unrestricted areas without any restrictive assumptions. Records of these measurements can then be evaluated to ensure that rates in unrestricted areas do not exceed the 1 mSv/yr (100 mrem/yr) limit.

Note: TLDs used for personnel monitoring (e.g., LiF) may not have sufficient sensitivity for this purpose. Generally, the minimum reportable dose received is 0.1 mSv (10 mrem). Suppose a TLD monitors dose received and is changed once a month. If the measurements are at the minimum reportable level, the annual dose received could have been about 1.2 mSv (120 mrem), a value in excess of the 1 mSv/yr (100 mrem/yr) limit. If licensees use TLDs to evaluate compliance with the public dose limits, they should consult with their TLD supplier and choose more sensitive TLDs, such as those containing CaF_2 that are used for environmental monitoring.

Example 2

As in Example 1, Joe is the RSO of a sealed source licensee. The company has three sealed sources stored in a designated, locked storage area that adjoins an unrestricted area where a secretarial workstation is located. See **Figure 3** and **Table 3** for information. Joe wants to see if the company complies with the public dose limits at the secretarial station.

During the winter while all the gauges are in storage, Joe placed an environmental TLD badge in the secretarial workspace for 30 days. Joe chose a winter month so he did not have to keep track of the number of hours that each sealed source was in the storage area. The TLD processor sent Joe a report indicating the TLD received 100 mrem.

Table 12. Combination Measurement-Calculation Method

Step No.	Description	Input Data and Results
PART 1		
1	**Dose** received by **TLD**, in mrem	**100**
2	**Total hours TLD** exposed	24 hr/d x 30 d/mo = **720**
3	Divide the results of Step 1 by the results of Step 2 to determine **HOURLY DOSE RECEIVED**, in mrem in an hour	**0.14**
4	Multiply the results of Step 3 by 365 d/yr x 24 hr/d = 8760 hours in one year = **MAXIMUM ANNUAL DOSE RECEIVED FROM SEALED SOURCES**, in mrem in a year	365 x 24 x 0.14 = 8760 x 0.14 = **1226**

Note: For the conditions described above, Step 3 indicates that the dose received in any one hour is less than the 2 mrem in any one hour limit. However, if there are any changes, then the licensee would need to reevaluate the potential doses which could be received in any one hour. Step 4 indicates that the annual dose received would be much greater than the 100 mrem in a year allowed by the rule.

PART 2

At this point Joe can adjust for a realistic estimate of the time the secretary spends in the area as he did in Part 2 of Example 1.

PART 3

If the results of Joe's evaluation in Part 2 show that the annual dose received in a year exceeds 100 mrem, then he can make adjustments for realistic estimates of the time spent in the area of concern while the sealed sources are actually in storage as in Part 3 of Example 1. (Recall that the TLD measurement was made while all the sealed sources are in storage--i.e. 24 hr/d for the 30 days that the TLD was in place.)

Appendix J:

Leak Test Program

Leak Test Program

Training

Before allowing an individual to perform leak testing, the RSO will ensure that he or she has sufficient classroom and on-the-job training to show competency in performing leak tests independently.

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 the use of instruments;
- Mathematics and calculations basic to the use and measurement of radioactivity; and
- Biological effects of radiation.

Appropriate on-the-job-training consists of:

- Observing authorized personnel collecting and analyzing leak test samples;
- Collecting and analyzing leak test samples under the supervision and in the physical presence of an individual authorized to perform leak tests.

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests will be analyzed in a low-background area.
- Before leak test swipes are analyzed, individuals conducting leak tests will use a calibrated and operable survey instrument to check leak test samples for gross contamination. If the sensitivity of the counting system is unknown, the minimum detectable activity (MDA) needs to be determined. The MDA may be determined using the following formula:

$$MDA = \frac{3 + 4.65(BR)*½}{Et}$$

where MDA = activity level in disintegrations per minute (dpm)
BR = background rate in counts per minute (cpm)
t = counting time in minutes
E = detector efficiency in counts per disintegration (cpd)

For example:

$$MDA = \frac{3 + 4.65(200\ cpm)*½}{(0.1\ cpd)(2\ minutes)}$$

where BR = 200 cpm
E = 0.1 cpd (10% efficient)
t = 2 minutes

- An NaI(Tl) well counter system with a single or multichannel analyzer will be used to count samples from sealed sources containing gamma-emitters (e.g., Cs-137, Co-60).
- A liquid scintillation or gas-flow proportional counting system will be used to count samples from sealed sources containing beta-emitters (e.g., Sr-90) or alpha emitters (e.g., Am-241).

Frequency for Conducting Leak Tests of Sealed Sources

- Leak tests will be conducted at the frequency specified in the respective Sealed Source and Device Registration Certificate.

Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as serial number, radionuclide, 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 where contamination would accumulate if the sealed source was leaking.
- Select an instrument that is sensitive enough to detect 185 Bq (0.005 microcurie) of the radionuclide contained in the gauge.
- Using the selected instrument, count and record background count rate.
- Check the instrument's counting efficiency using standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within +/-5 percent of the stated value and traceable to a primary radiation standard such as those maintained by the National Institutes of Standards and Technology (NIST).
- 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 Bq (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.
- If the wipe test activity is 185 Bq (0.005 microcurie) or greater, notify the RSO so that the source can be withdrawn from use and disposed of properly. Also notify VDH.

Appendix K:

Major DOT Regulations; Sample Bill of Lading

The major areas in the DOT regulations that are most relevant for transportation of typical sealed sources that are shipped as Type A quantities are as follows:

- Table of Hazardous Materials and Special Provisions **49 CFR 172.101**, and App. A, Table 2: Hazardous materials table, list of hazardous substances and reportable quantities
- 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 172.516, 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, RADIOACTIVE placard
- 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
- Radiation Protection Program for Shippers and Carriers, Subpart I, **49 CFR 172.800**, etc.
- 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 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.475, 49 CFR 173.476**: Definitions, general design requirements, additional design requirements for Type A packages, authorized Type A packages, requirement for determining A_1 and A_2, table of A_1 and A_2 values for radionuclides, radiation level limit, quality control requirements prior to each shipment, approval of special form radioactive materials
- 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 (secured against movement), Class 7 (radioactive) material

Minimum Required Packaging For Class 7 (Radioactive) Materials

This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials.

Quantity:	< 70 Bq/g (< 0.002 µCi/g)	Limited Quantity (§173.421)	A_1/A_2 value (§173.435)	1 rem/hr at 3 m, un-shielded (§173.427)
Non-LSA/SCO:	**Excepted**	**Type A**	**Type B [3]**	
Domestic or International LSA/SCO: • LSA-I solid, (liquid)[1] • SCO-I	Excepted	IP-I		Type B [3]
• LSA-I Liquid • LSA-II Solid, (liquid or gas)[1] • (LSA-III)[1] • SCO-II		IP-II		Type B [3]
• LSA-II Liquid or Gas • LSA-III		IP-III		Type B [3]
Domestic (only) LSA/SCO: • LSA-I, II, III; SCO-I, II	Excepted	Strong-tight [2]	DOT Spec. 7A Type A	Type B [3] NRC Type A LSA [3,4]

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]		

1. For entries in parentheses, exclusive use is required for shipment in an IP (e.g., shipment of LSA-I liquid in an IP-I packaging would require exclusive-use consignment)
2. Exclusive use required for strong-tight container shipments made pursuant to §173.427(b)(2)
3. Subject to conditions in Certificate, if NRC package
4. Exclusive use required, see §173.427(b)(4). Use of these packages expires on 4/1/99 (10 CFR 71.52)

A. The limits in this table do not apply to excepted packages - see 49 CFR 173.421-426.
B. Securely attached (to vehicle), access-limiting enclosure; package personnel barriers are considered as enclosures.
C. For nonfissile radioactive materials packages, the dimensionless number equivalent to maximum radiation level at 1 m (3.3 feet) from the exterior package surface, in millirem/hour.
D. No dose limit is specified, but separation distances apply to Radioactive Yellow-II or Radioactive Yellow-III labeled packages.
E. This does not apply to private carrier wearing dosimetry if under radiation protection program satisfying 10 CFR 20 or 49 CFR 172 Subpart I.
F. Some fissile shipments may have combined conveyance TI limit of 100 - see 10 CFR 71.59 and 49 CFR 173.457.

Hazard Communications for Class 7 (Radioactive) Materials

DOT Shipping Papers (49 CFR 172.200-205)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments. This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials.

Entries Always Required Unless Excepted

- The basic description, In sequence:

  Proper Shipping Name,
  Hazard Class (7),
  U.N. Identification Number
- 24 hour **emergency response telephone number**
- Name of **shipper**
- Proper page numbering (Page 1 of 4)
- Except for empty and bulk packages, the **total quantity** (mass, or volume for liquid), in appropriate units (lbs, mL....)
- If not special form, **chemical and physical form**
- The **name of each radionuclide** (95 percent rule) and total package activity. The activity must be in SI units (e.g., Bq, TBq), or both SI units and customary units (e.g., Ci, mCi). However, for domestic shipments, the activity *may* be expressed in terms of customary units only, until 4/1/97.
- For each labeled package:
  - The **category of label** used;
  - The **transport index** of each package with a Yellow-II or Yellow-III label
  - Shipper's **certification** (not required of private carriers)

Additional Entries Sometimes Required

Materials-Based Requirements

- If hazardous substance, "RQ" as part of the basic description
- The LSA or SCO group (e.g., LSA-II)
- "Highway Route Controlled Quantity" as part of the basic description , if HRCQ
- Fissile material information (e.g., "Fissile Exempt," controlled shipment statement [see §172.203(d)(7)])
- If the material is considered hazardous waste and the word waste does not appear in the shipping name, then "waste" must precede the shipping name (e.g., Waste Radioactive Material, nos, UN2982)
- "Radioactive Material" if not in proper shipping name

Package-Based Requirements

- Package identification for DOT Type B or NRC certified packages
- IAEA CoC ID number for export shipments or shipments using foreign-made packaging (see §173.473)

Administrative-Based Requirements

- "Exclusive Use-Shipment"
- Instructions for maintenance of exclusive use-shipment controls for LSA/SCO strong-tight or NRC certified LSA (§ 173.427)
- If a DOT exemption is being used, "DOT-E" followed by the exemption number

Optional Entries

- The type of packaging (e.g., Type A, Type B, IP-1, ...)
- The technical/chemical name may be in included (if listed in §172.203(k), in parentheses between the proper shipping name and hazard class; otherwise inserted in parenthesis after the basic description)
- Other information is permitted (e.g., functional description of the product), provided it does not confuse or detract from the proper shipping name or other required information
- For fissile radionuclides, except Pu-238, Pu-239, and Pu-241, the weight in grams or kilograms may be used *in place of* activity units. For Pu-238, Pu-239, and Pu-241, the weight in grams or kilograms may optionally be entered *in addition to* activity units [see §172.203(d)(4)]
- Emergency response hazards and guidance information (§§172.600-604) may be entered on the shipping papers, or may be carried with the shipping papers [§172.602(b)]

Some Special Considerations/Exceptions for Shipping Paper Requirements

- Shipments of Radioactive Material, excepted packages, under UN2910 (e.g., Limited Quantity, Empty packages, and Radioactive Instrument and Article), are excepted from shipping papers. For limited quantities (§173.421), this is only true if the limited quantity is not a hazardous substance (RQ) or hazardous waste (40 CFR 262).
- Shipping papers must be in the pocket on the left door, or readily visible to a person entering the driver's compartment and within arm's reach of the driver.
- For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, be designated by an "X" (or "RQ") in the hazardous material column, *or* be highlighted in a contrasting color.

Hazard Communications for Class 7 (Radioactive) Materials

Marking Packages (49 CFR 172.300-338)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments. This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials.

Markings Always Required Unless Excepted

Non-Bulk Packages

- Proper shipping name
- U.N. identification number
- Name and address of consignor or consignee, *unless*:
  1. highway only and no motor carrier transfers; *or*

  part of carload or truckload lot or freight container load, and entire contents of railcar, truck, or freight container are shipped from one consignor to one consignee [see §172.301(d)]

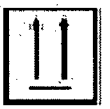
Bulk Packages (i.e., net capacity greater than 119 gallons as a receptacle for liquid, or 119 gallons and 882 pounds as a receptacle for solid, or water capacity greater than 1000 lbs, with no consideration of intermediate forms of containment)

- U.N. identification number, on orange, rectangular panel (see §172.332) - some exceptions exist

Additional Markings Sometimes Required

Materials-Based Requirements

- If in excess of 110 lbs (50 kg), Gross Weight
- If non-bulk *liquid* package, underlined double arrows indicating upright orientation (two opposite sides) [ISO Std 780-1985 marking]



- If a Hazardous substance in non-bulk package, the letters "RQ" in association with the proper shipping name

Package-Based Requirements

- The package type if Type A or Type B (½" or greater letters)
- The specification-required markings [e.g., for Spec. 7A packages: "DOT 7A Type A" and "Radioactive Material" (see §178.350-353)]
- For approved packages, the certificate ID number (e.g., USA/9166/B(U), USA/9150/B(U)-85, ...)
- If Type B, the trefoil (radiation) symbol per Part 172 App. B [*size*: outer radius ≥ 20 mm (0.8 in)]
- For NRC certified packages, the model number, gross weight, and package ID number (10 CFR 71.85)

Administrative-Based Requirements

- If a DOT exemption is being used, "DOT-E" followed by the exemption number
- If an export shipment, "USA" in conjunction with the specification markings or certificate markings

Optional Markings

- "IP-1," "IP-2," or "IP-3" on industrial packaging is recommended
- Both the name and address of consignor and consignee are recommended
- Other markings (e.g., advertising) are permitted, but must be sufficiently away from required markings and labeling

Some Special Considerations/Exceptions for Marking Requirements

- Marking is required to be: (1) durable, (2) printed on a package, label, tag, or sign, (3) unobscured by labels or attachments, (4) isolated from other marks, and (5) be representative of the hazmat contents of the package.
- Limited Quantity (§173.421) packages and Articles Containing Natural Uranium and Thorium (§173.426) must bear the marking "radioactive" on the outside of the inner package or the outer package itself, and are excepted from other marking. The excepted packages shipped under UN 2910 must also have the accompanying statement that is required by §173.422.
- Empty (§173.428) and Radioactive Instrument and Article (§173.424) packages are excepted from marking.
- Shipment of LSA or SCO required by §173.427 to be consigned as exclusive use are excepted from marking except that the exterior of *each* nonbulk package must be marked "**Radioactive-LSA**" or "**Radioactive-SCO**," as appropriate. Examples of this category are domestic, strong-tight containers with less than an A_2 quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52.
- For bulk packages, marking may be required on more than one side of the package (see 49 CFR 172.302(a)).

Hazard Communications for Class 7 (Radioactive) Materials

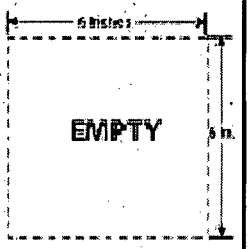
Labeling Packages (49 CFR 172.400-450)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments. This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials.

Placement of Radioactive Labels

- Labeling is required to be: (1) placed near the required marking of the proper shipping name, (2) printed or affixed to the package surface (not the bottom), (3) in contrast with its background, (4) unobscured by markings or attachments, (5) within color, design, and size tolerance, and (6) representative of the HAZMAT contents of the package.
- For labeling of radioactive materials packages, two labels are required on opposite sides excluding the bottom.

Determination of Required Label

Size: *Sides:* ≥ 100 mm (3.9 in.) *Border:* 5-6.3 mm (0.2-0.25 in.)	 49 CFR 172.436	 49 CFR 172.438	 49 CFR 172.440	 49 CFR 172.450
Label	**WHITE-I**	**YELLOW-II**	**YELLOW-III**	**EMPTY LABEL**
Required when:	Surface radiation level < 0.005 mSv/hr (0.5 mrem/hr)	0.005 mSv/hr (0.5 mrem/hr) < surface radiation level ≤ 0.5 mSv/hr (50 mrem/hr)	0.5 mSv/hr (50 mrem/hr) < surface radiation level ≤ 2 mSv/hr (200 mrem/h) [Note: 10 mSv/hr (1000 mrem/hr) for exclusive-use closed vehicle (§173.441(b)]	The EMPTY label is required for shipments of empty Class 7 (radioactive) packages made pursuant to **§173.428**. It must cover any previous labels, or they must be removed or obliterated.
Or:	TI = 0 [1 meter dose rate < 0.0005 mSv/hr (0.05 mrem/hr)]	TI ≤ 1 [1 meter dose rate < 0.01 mSv/hr (1 mrem/hr)]	TI ≤ 10 [1 meter dose rate < 0.1 mSv/hr (10 mrem/hr)] [Note: There is no *package* TI limit for exclusive-use]	
Notes:	• Any package containing a Highway Route Controlled Quantity (HRCQ) **must bear YELLOW-III label** • Although radiation level transport indices (TIs) are shown above, for fissile material, the TI is typically determined on the basis of criticality control			

Content on Radioactive Labels

2. RADIOACTIVE Label must contain (entered using a durable, weather-resistant means):
   (1) The radionuclides in the package (with consideration of available space). Symbols (e.g., Co-60) are acceptable.
   (2) The activity in SI units (e.g., Bq, TBq), or both SI units with customary units (e.g., Ci, mCi) in parenthesis. However, for domestic shipments, the activity *may* be expressed in terms of customary units only, until 4/1/97.
   (3) The Transport Index (TI) in the supplied box. The TI is entered *only* on YELLOW-II and YELLOW-III labels.

Some Special Considerations/Exceptions for Labeling Requirements

- For materials meeting the definition of another hazard class, labels for each secondary hazard class need to be affixed to the package. The subsidiary label *may* not be required on opposite sides, and must not display the hazard class number.
- Radioactive Material, excepted packages, under UN2910 (e.g., Limited Quantity, Empty packages, and Radioactive Instrument and Article), are excepted from labeling. However, if the excepted quantity meets the definition for another hazard class, it is re-classed for that hazard. Hazard communication requirements for the other class are required.
- Labeling exceptions exist for shipment of LSA or SCO required by § 173.427 to be consigned as exclusive use.
- The "Cargo Aircraft Only" label is typically required for radioactive materials packages shipped by air [§ 172.402(c)].

Hazard Communications for Class 7 (Radioactive) Materials

Placarding Vehicles (49 CFR 172.500-560)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments. This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials.

Visibility and Display of Radioactive Placard

- Placards are required to be displayed:
  - On four sides of the vehicle;
  - Visible from the direction they face, (for the front side of trucks, tractor-front, trailer, or both are authorized);
  - Clear of appurtenances and devices (e.g., ladders, pipes, tarpaulins);
  - At least 3 inches from any markings (such as advertisements) which may reduce placard's effectiveness;
  - Upright and on-point such that the words read horizontally;
  - In contrast with the background, or have a lined-border which contrasts with the background;
  - Such that dirt or water from the transport vehicle's wheels will not strike them;
  - Securely attached or affixed to the vehicle, or in a holder.
- Placard must be maintained by carrier to keep color, legibility, and visibility.

Conditions Requiring Placarding

- Placards are required for any vehicle containing a package with a RADIOACTIVE Yellow-III label.
- Placards are required for shipment of LSA or SCO required by §173.427 to be consigned as exclusive use. Examples of this category are domestic, strong-tight containers with less than an A_2 quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52. Also, for bulk packages of these materials, the orange panel marking with the UN Identification number is not required.
- Placards are required for any vehicle containing a package with a Highway Route Controlled Quantity (HRCQ). In this case, the placard must be placed in a square background as shown below (see §173.507(a)).

Radioactive Placard

Size Specs: *Sides:* ≥ 273 mm (10.8 in.) *Solid line Inner border:* About 12.7 mm (0.5 in.) from edges *Lettering:* ≥ 41 mm (1.6 in.) *Square for HRCQ:* 387mm (15.25 in.) outside length by 25.4 mm (1 in.) thick	 49 CFR 172.556	 IAEA SS 6 (1985) paras. 443-444	 See 49 CFR 172.527 AND 556
	RADIOACTIVE PLACARD (Domestic) *Base of yellow solid area:* 29 ± 5 mm (1.1 ± 0.2 in.) above horizontal centerline	**RADIOACTIVE PLACARD (International)**	**RADIOACTIVE PLACARD FOR HIGHWAY ROUTE CONTROLLED QUANTITY** (either domestic or international placard could be in middle)

Some Special Considerations/Exceptions for Placarding Requirements

- Domestically, substitution of the UN ID number for the word "RADIOACTIVE" on the placard is prohibited for Class 7 materials. However, some import shipments may have this substitution in accordance with international regulations.
- Bulk packages require the orange, rectangular panel marking containing the UN ID number, which must be placed adjacent to the placard (see §172.332) [NOTE: except for LSA/ SCO exclusive use under §173.427, as above].
- If placarding for more than one hazard class, subsidiary placards must not display the hazard class number. Uranium Hexafluoride (UF_6) shipments ≥ 454 kg (1001 lbs) require both RADIOACTIVE and CORROSIVE (Class 8) placarding.
- For shipments of radiography cameras in convenience overpacks, if the overpack does not require a RADIOACTIVE – YELLOW III label, vehicle placarding is not required (regardless of the label which must be placed on the camera).

Package and Vehicle Contamination Limits (49 CFR 173.443)

This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

NOTE: All values for contamination in DOT rules are to be averaged over each 300 cm^2
Sufficient measurements must be taken in the appropriate locations to yield representative assessments

$\beta\gamma$ means the sum of beta emitters, gamma emitters, and low-toxicity alpha emitters
* means the sum of all other alpha emitters (i.e., other than low-toxicity alpha emitters)

The Basic Contamination Limits for All Packages: 49 CFR 173.443(a), Table 11	General Requirement: Non-fixed (removable) contamination must be kept as low as reasonably achievable (ALARA)
	$\beta\gamma$: 0.4 Bq/cm^2 = 40 Bq/100 cm^2 = $1x10^{-5}$ µCi/cm^2 = 2200 dpm/100 cm^2
	α: 0.04 Bq/cm^2 = 4 Bq/100 cm^2 = $1x10^{-6}$ µCi/cm^2 = 220 dpm/100 cm^2

The following exceptions and deviations from the above basic limits exist:

Deviation from Basic Limits	**Regulation 49 CFR §§**	**Applicable Location and Conditions Which must Be Met:**
10 times the basic limits	173.443(b) and 173.443(c) Also see 177.843 (highway)	On any external surface of a package in an exclusive use shipment, during transport including end of transport. Conditions include: • Contamination levels at beginning of transport must be below the basic limits. • Vehicle must not be returned to service until radiation level is shown to be ≤ 0.005 mSv/hr (0.5 mrem/hr) at any accessible surface, and there is no significant removable (non-fixed) contamination.
10 times the basic limits	173.443(d) Also see 177.843 (highway)	On any external surface of a package, at the beginning or end of transport, if a closed transport vehicle is used, solely for transporting radioactive materials packages. Conditions include: • A survey of the interior surfaces of the empty vehicle must show that the radiation level at any point does not exceed 0.1 mSv/hr (10 mrem/hr) at the surface, or 0.02 mSv/hr (2 mrem/hr) at 1 meter (3.3 ft). • Exterior of vehicle must be conspicuously stenciled, "For Radioactive Materials Use Only" in letters at least 76 mm (3 inches) high, on both sides. • Vehicle must be kept closed except when loading and unloading.
100 times the basic limits	173.428	**Internal** contamination limit for excepted package-empty packaging, Class 7 (Radioactive) Material, shipped in accordance with 49 CFR 173.428. Conditions include: (1) The basic contamination limits (above) apply to **external** surfaces of package. (2) Radiation level must be ≤ 0.005 mSv/hr (0.5 mrem/hr) at any external surface. (3) Notice in §173.422(a)(4) must accompany shipment. (4) Package is in unimpaired condition & securely closed to prevent leakage. (5)Labels are removed, obliterated, or covered, and the "empty" label (§172.450) is affixed to the package.

In addition, after any incident involving spillage, breakage, or suspected contamination, the modal-specific DOT regulations (§177.861(a), highway; §174.750(a), railway; and §175.700(b), air) specify that vehicles, buildings, areas, or equipment have "no significant removable surface contamination" before being returned to service or routinely occupied. The carrier must also notify offeror at the earliest practicable moment after incident.

Sample Bill of Lading

Appendix K --

STRAIGHT BILL OF LADING

ORIGINAL — NOT NEGOTIABLE

Shipper No. ____ ____

Carrier No ____ ____

Page 1 of 1 (Name of carrier) (SCAC) Date ____ ____

TO: Consignee: Builders, Inc. **	FROM: Shipper: Moisture Density Measurements, Inc. **
On Collect on Delivery shipments, the letters "COD" must appear before consignee's name or as otherwise provided in Item 430, Sec. 1.	
Street: 5678 Jefferson Davis Highway **	Street: 1234 A Street, NW **
Destination: Arlington, VA** Zip Code: 22222**	Origin: Washington, DC 20000**
Route:	Vehicle Number:

No. of Units & Container Type	HM	BASIC DESCRIPTION (Proper Shipping Name, Hazard Class, Identification Number (UN or NA) per 172.101, 172.202, 172.203)	TOTAL QUANTITY (Weight, Volume, Gallons, etc.)	WEIGHT (Subject to Correction)	RATE	CHARGES (For Carrier Use Only)
1	RQ	Radioactive material, special form				
		n.o.s. 7 UN2974				
		0.41GBq (11 mCi) Cs-137 and				
		1.9GBq (50 mCi) Am-241:Be	2.31 GBq			
			(61 mCi)			
		RADIOACTIVE - YELLOW II				
		TI = 0.4 **				
		USDOT 7A TYPE A				
		Emergency Response Telephone No.: 1-800-000-0000 (24 hr/d)**				
		** SUBSTITUTE APPROPRIATE INFORMATION FOR				
		YOUR GAUGE AND YOUR SHIPMENT				

PLACARDS TENDERED: YES ☐ NO ☐

REMIT C.O.D. TO: ADDRESS

Note — Where the rate is dependent on value, shippers are required to state specifically in writing the agreed or declared value of the property.
The agreed or declared value of the property is hereby specifically stated by the shipper to be not exceeding
$ _____ per _____

I hereby declare that the contents of this consignment are fully and accurately described above by proper shipping names and are classified, packaged, marked and labeled, and are in all respects in proper condition for transport by [illegible] regulations [illegible] ACCURATE NON-APPLICABLE BOOK OF TRANSPORT according to applicable international and national governmental regulations

John Jones
Signature

COD Amt: $

Subject to Section 7 of the conditions, if this shipment is to be delivered to the consignee without recourse on the consignor, the consignor shall sign the following statement
The carrier shall not make delivery of this shipment without payment of freight and all other lawful charges.
_____ (Signature of Consignor)

C.O.D. FEE: PREPAID ☐ COLLECT ☐ $

TOTAL CHARGES: $

FREIGHT CHARGES: Freight Prepaid unless otherwise specified. Check box if charges are to be collected ☐

RECEIVED, subject to the classifications and tariffs in effect on the date of the issue of this Bill of Lading, the property described above in apparent good order, except as noted (contents and condition of contents of packages unknown), marked, consigned, and destined as indicated above which said carrier (the word carrier being understood throughout this contract as meaning any person or corporation in possession of the property under the contract) agrees to carry to its usual place of delivery at said destination, if on its route, otherwise to deliver to another carrier on the route to said destination. It is mutually agreed, as to each carrier of all or any of said property over all or any portion of said route to destination and as to each party at any time interested in all or any said property, that every service to be performed hereunder shall be subject to all the terms and conditions of the governing classification on the date of shipment.
Shipper hereby certifies that he is familiar with all the bill of lading terms and conditions in the governing classification and the said terms and conditions are hereby agreed to by the shipper and accepted for himself and his assigns.

SHIPPER	CARRIER
PER	PER
	DATE

1

Permanent post office address of shipper.

STYLE F65 LABELMASTER Div. of American Labelmark Co., Chicago, IL 60646 312/478-0900

Appendix L

Sample Correspondence Letter

SAMPLE CORRESPONDENCE DELEGATION LETTER

[date]

Virginia Department of Health
Radioactive Materials Program
109 Governor Street, Room 730
Richmond, VA 23219

To Radioactive Material Program Director:

As [job title] of [name of licensee], I have delegated authority for all matters pertaining to our Virginia 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