Commonwealth of Virginia
Radiation Protection Regulatory Guide

Guidance for Medical Use of Radioactive Material

EPI-720 G

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Radioactive Materials Program
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EXECUTIVE SUMMARY

Virginia Regulatory Guides **(VAREGS)** are issued to describe and make available to the applicant or licensee, acceptable methods of implementing specific parts of 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 vitr*o, 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
12VAC5-481-2020	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.

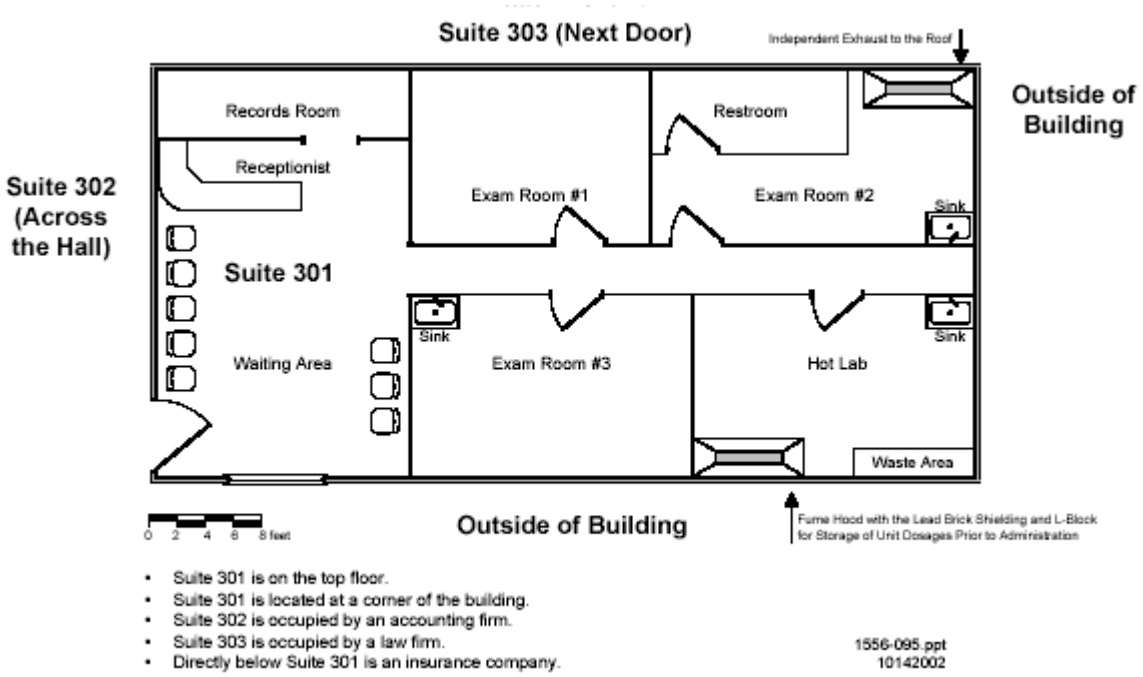

Figure 1: Facility Diagram for Nuclear Medicine Suite

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 rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys or leak testing and analysis.

AND ONE OF THE FOLLOWING

☐ We will use radiation monitoring instruments that will be calibrated by a person authorized by VDH, the NRC or another Agreement State to perform survey meter calibrations.

OR

☐ We will follow survey meter calibration procedures in accordance with Appendix I of VAREG 'Guidance for Medical Use of Radioactive Material'.

References: Copies of NRC NUREGs including NUREG-1556, Vol. 18, 'Program-Specific Guidance About Service Provider Licenses', dated November 2000 can be accessed at NRC's web site, http://www.nrc.gov.

Item 8.3: Dose Calibrator and other Equipment used to Measure Dosages of Unsealed Radioactive Material

Rule: 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 vitr*o) 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 "S*hallow 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 'Guidance for 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
(804) 864-8150

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE FOR MEDICAL USE

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

Instructions: Complete all items if this is an initial application or an application for renewal of a license. Refer to VAREG 'Guidance for Medical Use of Radioactive Material'. Use supplementary sheets where necessary. Retain one copy and submit original of the entire application to Virginia Department of Health, Radioactive Materials Program 109 Governor Street, Room 730, Richmond, VA 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 **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**.

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; 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; 12VAC5-481-2030; 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.

AND, IF APPLICABLE

☐ We will provide a description of recent related continuing education and experience as required by **12VAC5-481-1790**.

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 **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**.

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**.

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			
☐ 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			

Type of Use – Check Box if Use is Desired	Chemical and Physical Form	Maximum Amount (Curies)	Sealed Source Manufacturer or Distributor Model Number
☐ 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.		

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 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'.

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 **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 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 **12VAC5-481-760** that meets the requirements in **12VAC5-481 'Virginia 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 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, 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 **12VAC5-481-1900** & **12VAC5-481-1920**)

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)

LICENSE FEES

Item 11 License Fees (Refer to **12VAC5-491**.)

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 **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

RESERVED

Appendix C

VDH Form,
‘Certificate of Disposition of Materials’

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

CERTIFICATE OF DISPOSITION OF MATERIALS

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

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

CONTACT INFORMATION

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

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 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, ($1-e^{-0.693t/Tp}$) 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

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

Radionuclide	Physical Half-Life (days)[1]	Exposure Rate Constant [2] (R/mCi-h at 1 cm)
Ag-111	7.45	0.150
Au-198	2.696	2.3
Cr-51	27.704	0.16
Cu-64	0.529	1.2
Cu-67	2.578	0.58
F-18	0.076	6.95
Ga-67	3.261	0.753
I-123	0.55	1.61
I-125	60.14	1.42
I-125 implant	60.14	1.11[3]
I-131	8.04	2.2
In-111	2.83	3.21
Ir-192 implant	74.02	4.59[3]
P-32	14.29	NA[5]
Pd-103 implant	16.96	0.86[4]
Re-186	3.777	0.2
Re-188	0.708	0.26
Sc-47	3.351	0.56
Se-75	119.8	2.0
Sm-153	1.946	0.425
Sn-117m	13.61	1.48
Sr-89	50.5	NA[5]
Tc-99m	0.251	0.756
Tl-201	3.044	0.447
Y-90	2.67	NA[5]
Yb-169	32.01	1.83

1 K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, 'Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion,' Report No. EPA-520/1-88-020, Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, DC, 1988.

2 Values for the exposure rate constant for Au-198, Cr-51, Cu-64, F-18, I-131, Sc-47, and Se-75 were taken from the Radiological Health Handbook, U.S. Department of Health, Education, and Welfare, pp. 135, 1970. For Cu-67, I-123, In-111, Re-186, and Re-188, the values for the exposure rate constant were taken from D.E. Barber, J.W. Baum, and C.B. Meinhold, 'Radiation Safety Issues Related to Radiolabeled Antibodies,' NUREG/CR-4444, U.S. NRC, Washington, DC, 1991. For Ag-111, Ga-67, I-125, Sm-153, Sn-117m, Tc-99m, Tl-201, and Yb-169, the exposure rate constants were calculated because the published values for these radionuclides were an approximation, presented as a range, or varied from one reference to another. Details of the calculation of the exposure rate constants are shown in Table A.2 of Appendix A to NUREG-1492, 'Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material,' U.S. NRC, February 1997.

3 R. Nath, A.S. Meigooni, and J.A. Meli, 'Dosimetry on Transverse Axes of ^{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 (∞) = 4.59 mSv (0.459 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:

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

Where:
F_1 = Extrathyroidal uptake fraction;
F_2 = Thyroidal uptake fraction;
E_1 = Occupancy factor for the first 8 hours; and
E_2 = Occupancy factor from 8 hours to total decay.

All the other parameters are as defined in Equations B-1, B-3, and B-4. Acceptable values for F_1, T_{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 mSv (0.486 rem)

Therefore, hyperthyroid patients to whom 2035 megabecquerels (55 millicuries) of iodine-131 have been administered would not have to remain under licensee control and could be released under **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

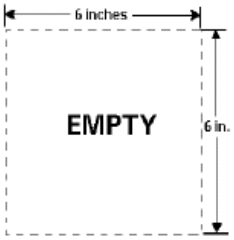
Labeling Packages (49 CFR 172.400-450)

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**