Commonwealth of Virginia
Radiation Protection Regulatory Guide

Guidance for Commercial Radiopharmacy

ORH-720 I

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

Revision 1

EXECUTIVE SUMMARY

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

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

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

This VAREG, 'Guidance for Commercial Radiopharmacy' has been developed to streamline the application process for a commercial radiopharmacy license. A copy of the VDH form 'Application for a Radioactive Material License for Commercial Radiopharmacies' is located in **Appendix A** of this guide.

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

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

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

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

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

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

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

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ABBREVIATIONS

ALARA	as low as is reasonably achievable
ALI	annual limit on intake
ANP	authorized nuclear pharmacist
ANSI	American National Standards Institute
AU	authorized user
bkg	background
BPR	business process redesign
Bq	becquerel
CDE	committed dose equivalent
CEDE	committed effective dose equivalent
CFR	Code of Federal Regulations
Ci	curie
cc	centimeter cubed
cm	centimeter
cm^2	centimeter squared
cpm	counts per minute
DAC	derived air concentration
DDE	deep-dose equivalent
DFP	decommissioning funding plan
DIS	decay in storage
DOE	United States Department of Energy
DOT	United States Department of Transportation
dpm	disintegrations per minute
dpm/cm^2	disintegrations per minute per square centimeter
EDE	effective dose equivalent
FA	financial assurance
FDA	United States Food and Drug Administration
GM	Geiger-Mueller
GPO	Government Printing Office
IN	Information Notice
IP	Inspection procedure
mCi	milliCurie
mGy	MilliGray
MDA	Minimum detectable activity
MOU	Memorandum of Understanding
mR	Milliroentgen
mrem	Millirem
mrem/hr	millirem per hour
mSv	Millisievert
mSv/hr	millisievert per hour
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NMSS	Office of Nuclear Materials Safety and Safeguards
NRC	Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OSL	Optically Stimulated Luminescence
PET	Positron Emission Tomography

P&GD	Policy and Guidance Directive
QA	quality assurance
R	roentgen
RG	Regulatory Guide
RQ	reportable quantity
RSO	radiation safety officer
SDE	Shallow-dose equivalent
SI	International System of Units (abbreviated SI from the French, Le Systeme Internationale d'Unites)
SSDR	Sealed Source and Device Registration
std	Standard
Sv	Sievert
TAR	Technical assistance request
TEDE	Total effective dose equivalent
TI	Transportation index
TLD	Thermoluminescent dosimeters
USDA	United States Department of Agriculture
VDH	Virginia Department of Health
µCi	microcurie
%	percent

PURPOSE OF GUIDE

This document provides guidance to an applicant in preparing a license application for a commercial radiopharmacy license. It also provides guidance on VDH's criteria for evaluating a commercial radiopharmacy license application. Within this guide, the terms, "commercial radiopharmacy," "radiopharmacy," "nuclear pharmacy," and "pharmacy" are used interchangeably.

Commercial radiopharmacy licenses are those licenses issued by VDH, pursuant to **12VAC5-481-480** for the possession and use of radioactive materials for the manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under **12VAC5-481-1670** through **12VAC5-481-2080**. Within this guide, preparation includes the making of radiopharmaceuticals from reagent kits (i.e., technetium-99m MAA (macroaggregated albumin)), and from raw materials (i.e., PET radiopharmaceuticals, the compounding of radioiodine capsules for diagnostic and therapeutic medical use). Commercial radiopharmacies may also be authorized to transfer for commercial distribution *in vitro* test kits described in **12VAC5-481-430 G**, radiopharmaceuticals to licensees authorized to possess them for other than human medical use (i.e., veterinary medicine and research licensees), and radiochemicals to those licensees authorized to possess them, pursuant to **12VAC5-481-430** and **12VAC5-481-500**. In addition, **12VAC5-481-480** authorizes radiopharmacies to redistribute (transfer) sealed sources for calibration and medical use initially distributed by a manufacturer licensed pursuant to **12VAC5-481-480**.

Specific guidance for applicants requesting to manufacture and initially distribute molybdenum-99/technetium-99m generators, *in vitro* kits, radiochemicals and sealed sources is included in NRC NUREG 1556, Vol. 12, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Manufacturing and Distribution Licenses', and is not within the scope of this VAREG. These activities require specific VDH, NRC or another Agreement State authorization and must be included on a specific license.

Furthermore, specific guidance for applicants requesting authorization to manufacture, distribute, and redistribute radioactive drugs to persons exempt from licensing (i.e., carbon-14 tagged urea) is included in NRC NUREG - 1556, Vol. 8, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Exempt Distribution Licenses', and also is not within the scope of this guidance.

This guide describes the information needed to complete VDH form, 'Application for a Radioactive Material License for Commercial Radiopharmacies' (**Appendix A**).

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

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

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

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

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

commonly used in medicine emit beta and photon radiation, for which the quality factor is 1; a useful rule of thumb is an exposure of 1 roentgen is equivalent to an absorbed dose of 1 rad and dose equivalent of 1 rem.

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

LICENSES

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

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

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

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

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

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

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

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

WHO REGULATES FACILITIES IN THE COMMONWEALTH OF VIRGINIA?

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

Table 1: Who Regulates the Activity?

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

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

MANAGEMENT RESPONSIBILITY

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

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

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

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

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

SAFETY CULTURE

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

Table 2: Traits of a Positive Nuclear Safety Culture

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

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

APPLICABLE RULE

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

The following parts of **12VAC5-481 'Virginia Radiation Protection Regulations'** contain requirements applicable to Commercial Radiopharmacy licenses:

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

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

HOW TO FILE

Applicants for a materials license should do the following:

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

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

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

WHERE TO FILE

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

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

LICENSE FEES

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

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

Direct all questions about VDH's fees or completion of **Item 16** of VDH form, 'Application for a Radioactive Material License for Commercial Radiopharmacies' ***(*Appendix A**) to Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, Virginia 23219 or (804) 864-8150.

CONTENTS OF AN APPLICATION

Item 1: Type of Application

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

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

Item 2: Name and Mailing Address of Applicant

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

Notify the agency of changes in mailing address.

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

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

Timely Notification of Change of Ownership or Control

Rule: 12VAC5-481-330, 12VAC5-481-400, 12VAC5-481-480, 12VAC5-481-490, 12VAC5-481-500

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

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

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

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

Notification of Bankruptcy Proceedings

Rule: 12VAC5-481-500

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

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

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

Item 3: Person to Contact Regarding Application

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

Discussion: This is typically the proposed radiation safety officer, unless the applicant has named a different person as the contact. The agency will contact this individual if there are questions about the application.

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

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

Rule: **12VAC5-481-450, 12VAC5-481-480, 12VAC5-481-500**

Criteria: Applicants need to provide a description of storage and use location.

Discussion: Specify the street address, city and state or other descriptive address (e.g., on Highway 58, 5 miles east of the intersection of Highway 58 and State Route 19, Anytown, VA) for each facility location. The descriptive address should be sufficient to allow a VDH inspector to find the use/storage location. **A Post Office Box address is not acceptable.**

If radioactive material is to be used at more than one location under the license, the specific address (e.g., street and building) must be provided for each facility.

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

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

Item 5: Radiation Safety Officer (RSO)

Rule: 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-480, 12VAC5-481-500

Criteria: Each licensee must appoint a qualified individual to act as the Radiation Safety Officer (RSO). The RSO must have adequate training and experience.

Discussion: VDH holds the licensee responsible for the radiation protection program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Senior management should delegate to the RSO, in writing, sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding **12VAC5-481 'Virginia Radiation Protection Regulations'**, license provisions and to terminate unsafe activities involving radioactive material. The applicant shall submit an organizational chart describing the management structure, reporting paths, and the flow of authority between executive management and the RSO. Management may delegate authority to the RSO to submit license amendments.

VDH requires the name, training, and experience of the proposed RSO to ensure that the applicant has identified a responsible qualified person to oversee the radiation safety program. When selecting an RSO, the applicant should keep in mind the duties and responsibilities of the position and select an individual who is qualified, and has the time and resources, to fulfill those duties and responsibilities. Typical duties and responsibilities of a radiopharmacy RSO are included in **Appendix H**.

The RSO needs a level of basic technical knowledge sufficient to understand the work to be performed with radioactive materials at the radiopharmacy and to be qualified by training and experience to perform the duties required for that position. Any individual who has sufficient training and experience to be named as an Authorized Nuclear Pharmacist (ANP) is also considered qualified to serve as the facility RSO. The same is true for an Authorized User (AU) who has had adequate training and experience in the radiation safety aspects associated with the use of similar types of radioactive material.

The training and experience requirements for the RSO may be met by any of the following:

- Qualification as an ANP;
- Identification as an AU on the license and experience in the use of the types and quantities of radioactive material for which the individual has RSO responsibilities; or
- Didactic and work experience.

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

- Radiation protection principles;
- Characteristics of ionizing radiation;
- Units of radiation dose and quantities;
- Radiation detection and measurement instrumentation;
- Biological hazards of exposure to radiation (appropriate to types and forms of radioactive material to be used);
- VDH requirements and standards; and
- Hands-on use of radioactive materials commensurate with the uses proposed by the applicant.

The length of training and experience will depend upon the type, form, quantity, and proposed use of the radioactive material requested. The proposed RSO's training and experience should be sufficient to identify and control the anticipated radiation hazards. The requisite training may be obtained from formal courses consisting of lectures and laboratories designed for RSOs presented by academic institutions, commercial radiation safety consulting companies, or appropriate professional organizations. Each hour of training may be counted only once and should be allocated to the most representative topic.

On-the-job training may not be counted toward the hours documenting length of training unless it was obtained as part of a formal training course. A ‘formal’ training course is one that incorporates the following elements:

- A detailed description of the content of the course is maintained on file at the sponsoring institution and can be made available to the agency upon request;
- Evidence that the sponsoring institution has examined the student's knowledge of the course content is maintained on file at the institution and can be made available to the agency upon request. This evidence of the student's overall competency in the course material should include a final grade or percentile; and
- A permanent record that the student successfully completed the course is kept at the institution.

Note: See **Appendix G** for convenient formats to use for documenting hours of training in basic radioisotope handling techniques and hours of experience using radioisotopes.

Item 6: Authorized Nuclear Pharmacist (ANP)

Rule: 12VAC5-481-10, 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-480, 12VAC5-481-1690, 12VAC5-481-1710, 12VAC5-481-1770, 12VAC5-481-1780, 12VAC5-481-1790

Criteria: ANP must be a state-licensed pharmacist with adequate training and experience.

Discussion: Each commercial nuclear pharmacy must have an ANP to prepare or supervise the preparation of radioactive drugs for medical use. Any individual who is not qualified to be an ANP may work under the supervision of an ANP.

The criteria for a pharmacist to work as an ANP at a commercial radiopharmacy are described in **12VAC5-481-480 I**. This section of the rule refers to the definition of an ANP in **12VAC5-481-10**, training and experience criteria described in **12VAC5-481-1770**, and recentness criteria described in

12VAC5-481-1790. Successful completion of training as described in **12VAC5-481-1790**, within 7 years proceeding the date of the application, is evidence of adequate training and experience. Additional training and experience may be necessary if the time interval is greater than 7 years. Applicants may find it convenient to present this documentation using formats similar to those found in **Appendix G**. Each hour of training may be listed only once (i.e., under the most applicable category). The recentness of training requirements applies to board certification as well as to other recognized training pathways.

On-the-job training may not be counted toward the hours listed above unless it was obtained as part of a formal training course. A 'formal' training course is one that incorporates the following elements:

- A detailed description of the content of the course is maintained on file at the sponsoring facility or institution and can be made available to the agency upon request;
- Evidence that the sponsoring facility or institution has examined the student's knowledge of the course content is maintained on file at the institution and can be made available to the the agency upon request. This evidence of the student's overall competency in the course material should include a final grade or percentile; and
- A permanent record that the student successfully completed the course is kept at the facility or institution.

Item 7: Authorized Users (AU)

Rule: 12VAC5-481-10, 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-1690, 12VAC5-481-1710, 12VAC5-481-1780, 12VAC5-481-1790

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

Discussion: If the applicant intends to perform functions other than the preparation and distribution of radioactive drugs, the applicant may request that an individual other than an ANP perform and/or supervise those functions. This individual, if approved, would be designated on the license as an AU. These other functions may include leak testing of sealed sources or instrument calibration services for the pharmacy; however, the term 'Authorized User', as used in this document should not be confused with the definition of an "*Authorized User*" contained in **12VAC5-481-10** for medical use.

Note: Licensees must apply for a service license if the applicant wishes to provide services such as leak testing of sealed sources or instrument calibration to their customers or others.

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

- Radiation protection principles;
- Characteristics of ionizing radiation;
- Units of radiation dose and quantities;
- Radiation detection and measurement instrumentation;
- Biological hazards of exposure to radiation (appropriate to types and forms of radioactive material to be used);
- VDH requirements and standards; and
- Hands-on use of radioactive materials commensurate with uses proposed by the applicant.

The length of training and experience listed above will depend upon the type, form, quantity, and proposed use of the radioactive material requested. The proposed AU's training and experience should be sufficient to identify and control the anticipated radiation hazards. The above training may be obtained from formal radiation safety courses consisting of lectures and laboratories presented by academic institutions, commercial radiation safety consulting companies, or appropriate professional organizations. Each hour of training may be counted only once and should be allocated to the most representative topic.

On-the-job training may not count toward the hours listed above unless it was obtained as part of a formal training course. A 'formal' training course is one that incorporates the following elements:

- A detailed description of the content of the course is maintained on file at the sponsoring facility or institution and can be made available to the agency upon request;
- Evidence that the sponsoring facility or institution has examined the student's knowledge of the course content is maintained on file at the facility or institution and can be made available to the agency upon request. This evidence of the student's overall competency in the course material should include a final grade or percentile; and
- A permanent record that the student successfully completed the course is kept at the facility or institution.

The AU must demonstrate training and experience with the type and quantity of material that is to be used at the pharmacy. For example, someone with training and experience only with microcurie quantities of unsealed radioactive material may not be qualified to use or supervise the use of higher activity sealed radioactive sources for instrument calibration. Applicants should pay particular attention to the type of radiation involved. For example, someone experienced with gamma emitters may not have appropriate experience for high-energy beta emitters.

Item 8: Training for Individuals Working in or Frequenting Restricted Areas

Item 8.1: Occupationally Exposed Workers and Ancillary Personnel

Rule: 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-480, 12VAC5-481-630, 12VAC5-481-2270, 12VAC5-481-2280

Criteria: Individuals working with radioactive material must receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program. In addition, those individuals who, in the course of employment, are likely to receive in a year a dose in excess of 100 mrem (1 mSv) must be instructed according to **12VAC5-481-2270.**

Discussion: 12VAC5-481-630 requires each licensee to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with of **12VAC5-481 'Virginia Radiation Protection Regulations,' Part IV, 'Standards For Protection Against Radiation'**. Each individual working with radioactive material must be trained in the radiation safety procedures applicable to their job before beginning work with radioactive materials. Licensees should not assume that safety instruction has been adequately covered by prior employment or training. Practical, site-specific training should be provided for all individuals prior to beginning work with, or in the vicinity of, licensed material. Training should also be performed whenever there is a significant change in duties, procedures, rules, or terms of the license.

Each individual that receives greater than 100 mrem (1 mSv) should also receive annual training as specified in **12VAC5-481-2270**. ANPs and others involved in the preparation of radiopharmaceuticals are most likely to receive doses in excess of 100 mrem (1 mSv) in a year; however, potential radiation doses received by all employees must also be evaluated. The evaluation must include consideration of assigned activities during both normal and abnormal situations involving exposure to radiation and/or radioactive material that can reasonably be expected to occur during licensed activities.

If individuals making deliveries of radioactive material at the licensees facility are likely to receive a dose in excess of 100 mrem (1 mSv) in a year from the licensees activities, the licensee is responsible for ensuring that the person has received the training specified in of **12VAC5-481 'Virginia Radiation Protection Regulations', Part X, 'Notices, Instructions and Reports to Workers'**, regardless of whether that person is an employee of the licensee. If the training has been provided by someone else (such as the shipper or another licensee), the licensee does not have to provide training except for instruction in site-specific radiation hazards. This issue is discussed in NRC Generic Letter 95-09, 'Monitoring and Training of Shippers and Carriers of Radioactive Materials,' dated November 3, 1995 which is available from the NRC website at www.nrc.gov.

Training may be in the form of lecture, demonstrations, videotape, or self-study, and should emphasize practical subjects important to the safe use of licensed material. A method should be provided for individuals receiving instructions and training to ask questions. The licensee should determine whether the training succeeded in conveying the desired information and adjust the training program as necessary. The person conducting the training should be a qualified individual (e.g., the RSO, an ANP, AU, or radiation safety professional familiar with the licensee's program).

Licensee personnel who work in the vicinity of, but do not handle radioactive materials (ancillary staff), are not required to have radiation safety training as long as they are not likely to receive 100 mrem (1 mSv) in a year; however, to minimize potential radiation exposure when ancillary staff are working in the vicinity of radioactive material, it is prudent for them to work under the supervision and in the physical presence of an ANP/AU or to be provided some basic radiation safety training. Such ancillary staff should be informed of the nature and location of the radioactive material and the meaning of the radiation symbol, and should be instructed not to handle radioactive materials and to keep away from it as much as their work permits.

Note: Some ancillary staff, although not likely to receive doses over 100 mrem (1 mSv), should receive training to ensure adequate security and control of licensed material. Licensees may provide these individuals with training commensurate with their assignments in the vicinity of the radioactive material to ensure the control and security of the material.

Note: The guidance in **Appendix N** may be used by the applicant to develop a training program.

References: NRC Generic Letter 95-09, 'Monitoring and Training of Shippers and Carriers of Radioactive Materials,' can be accessed at the NRC website www.nrc.gov under 'Electronic Reading Room', or contact VDH.

Item 8.2: Personnel Involved in Hazardous Materials Package Preparation and Transport

Rule: 12VAC5-481-2980, 49 CFR 172.700, 49 CFR 172.702, 49 CFR 172.704

Criteria: Applicants must train personnel involved in the preparation and transport of hazardous material packages in the applicable DOT regulations.

Discussion: Licensees who prepare packages of radioactive materials or who transport their own packages must provide training to their employees who perform those functions. The training must include:

- General awareness and familiarization training designed to provide familiarity with VDH and DOT requirements, and the ability of the employee to recognize and identify hazardous materials;
- Function-specific training concerning the VDH and DOT requirements that are specifically applicable to the functions the employee performs, (e.g., if the employee's duties require affixing DOT radioactive labels to packages, the employee must receive training in DOT's regulations governing package labeling); and
- Safety training concerning emergency response information, discussed above; measures to protect the employee and other employees from the hazards associated with the hazardous materials to which they may be exposed to in the workplace; and methods of avoiding accidents, such as the proper procedures for handling packages containing hazardous materials.

The training must be provided initially (within 90 days), and every 3 years thereafter. Records of training must be maintained.

Note: The licensee is not responsible for providing DOT-required hazardous materials training to common carriers to which the pharmacy offers radioactive materials packages for transport.

Item 8.3: Instruction for Supervised Individuals Preparing Radiopharmaceuticals

Rule: 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-480, 12VAC5-481-1710

Criteria: Individuals who prepare radioactive material for medical use under the supervision of an ANP must be instructed in the preparation of radioactive material for medical use, the principles of radiation safety, and the licensee's procedures for the use of radioactive material; follow the instructions given; and must have their work and records kept to reflect their work periodically reviewed by the supervising ANP.

Discussion: The applicant must instruct supervised individuals in the preparation of radioactive material for medical use and require those individuals to follow their instructions, the written radiation protection program, license conditions, and VDH rules. The supervising ANP must review the work of supervised individuals in the preparation of radioactive material for medical use and the records kept to reflect that work.

An ANP is considered to be supervising the use of radioactive materials when directing personnel in the conduct of operations involving licensed materials. The ANP need not be present at all times during the use of such materials; however, the supervising ANP is responsible for ensuring that personnel under supervision have been properly trained and instructed. This will be addressed by a condition on the radiopharmacy license. The supervising ANP is responsible for the supervision of operations involving the use of radioactive materials.

12VAC5-481 'Virginia Radiation Protection Regulations' does not relieve the licensee from complying with other applicable federal (Food and Drug Administration) and state requirements governing radioactive drugs.

Item 9: Radioactive Material

Part 1: Unsealed and/or Sealed Radioactive Material

Rule: 12VAC5-481-390, 12VAC5-481-440, 12VAC5-481-480, 12VAC5-481-500

Criteria: Applicants must submit information specifying each radionuclide requested; the form; and the maximum activity to be possessed at any one time. For sealed sources, the applicant must also submit the manufacturer and model number of each requested sealed source.

Discussion: Each authorized radioisotope is listed on a VDH license by its element name, form, and the maximum amount the licensee may possess at any one time (maximum possession limit).

The applicant should list each requested radioisotope by its element name and its mass number (e.g., Technetium-99m) in **Item 9**. It is necessary to specify whether the material will be acquired and used in unsealed or sealed form. The name of the specific chemical compound that contains the radioisotope is not generally required.

For unsealed radioactive material, it is also necessary to specify whether requested radioisotopes will be handled in volatile or non-volatile form, since additional safety precautions are required when handling and using material in a volatile form. For example, when requesting authorization to possess and distribute Iodine-131, the applicant must specify whether the material will be manipulated at the radiopharmacy in a volatile form (e.g., compounding of Iodine-131 capsules) or received in the form in which it will be distributed (e.g., redistribution of sealed, unopened vials of Iodine-131). Applicants requesting authorization to manipulate volatile radioactive material must describe appropriate facilities and engineering controls in response to **Item 13**, 'Facilities and Equipment', and radiation safety procedures for handling of such material in specific responses to **Item 14.4**, 'Occupational Dosimetry', **Item 14.5**, 'Public Dose', **Item 14.6**, 'Safe Use of Radionuclides and Emergency Procedures', and **Item 14.7**, 'Surveys'.

The anticipated possession limit in becquerels (Bq) or curies (Ci) for each radioisotope should also be specified. Possession limits must include the total anticipated inventory, including licensed material in storage and waste, and should be commensurate with the applicant's needs and facilities for safe handling. Applicants should review the requirements for submitting a certification for financial assurance for decommissioning before specifying possession limits of any radioisotope with a half-life greater than 120 days. These requirements are discussed in **Item 9, Part 4**.

Applicants will be authorized to possess and use only those sealed sources, such as calibration and reference sources that are specifically approved or registered by the NRC or another Agreement State. A safety evaluation of sealed sources and devices is performed by the NRC or another Agreement State before authorizing a manufacturer (or distributor) to distribute them to specific licensees. Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that the agency can verify that they have been evaluated in a Sealed Source and Device (SSD) Registration Certificate or specifically approved on a license. Before the formalization of the SSD

registration process, some older sources or devices may have been specifically approved on a license. Licensees can continue to use those sources and devices specifically listed on their licenses.

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

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

A safety evaluation of sealed sources and devices is performed by NRC or another Agreement State before authorizing a manufacturer (or distributor) to distribute them to specific licensees. The safety evaluation is documented in an SSD Registration Certificate. For additional guidance relating to sealed sources and devices, see also NUREG-1556, Vol. 3, "*Applications for Sealed Source and Device Evaluation and Registration*".

Note: If necessary and the manufacturer cannot supply the certificate, SSD Registration Certificates are also available by calling the agency at (804) 864-8150.

The applicant must also request authorization to possess depleted uranium if it will be used for shielding of molybdenum-99/technetium-99m generators. Depleted uranium is frequently used as shielding for generators when the molybdenum-99 activity is greater than 148 gigabecquerels (4 curies). **12VAC5-481-390** exempts depleted uranium from the requirements for a license to the extent that the material is used as a shipping container, such as when molybdenum-99/technetium-99m generators are in transit from their manufacturer to the pharmacy; however, a specific license or authorization from VDH is needed to possess and use the depleted uranium as a shield during the time that the pharmacy uses or stores the generator at its facility. The applicant must specify the total amount of depleted uranium, in kilograms, that will be needed.

If an applicant requests quantities of licensed material in excess of limits in **12VAC5-481-440 G** (for example, 10 curies of Iodine 131), the applicant must either submit an emergency plan for responding to a release of radioactive materials or perform an evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem (10 mSv) effective dose equivalent or 5 rems (50 mSv) to the thyroid.

Licensees must submit a license amendment and receive VDH authorization before they may make changes in the types, forms, and quantities of materials possessed.

Part 2: Sealed Sources for Calibration and Reference Sources

Rule: 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-480, 12VAC5-481-500

Criteria: The applicant must specify the uses for sealed sources for reference and calibration.

Discussion: The applicant should describe the intended use of sealed sources. This will normally be for calibration and checks performed only on the applicant's instruments and equipment. Any sources intended for use in a specific instrument calibration device should be identified, along with the manufacturer and model number of the device.

Part 3: Purpose(s) for which Radioactive Material Will Be Used

Rule: 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-480, 12VAC5-481-500

Criteria: Proposed activity is authorized by **12VAC5-481 'Virginia Radiation Protection Regulations'**.

Discussion: The distribution of radioactive materials by commercial radiopharmacies is authorized by several distinct rules. The appropriate rule to refer to depends on the nature of the material, the purpose(s) for which it will be used, and to whom it is sent. For example, see the following list:

- Possession and use of radioactive materials (**12VAC5-481-450**)
- Distribution of radiochemicals and radioactive drugs to veterinarians, laboratories and other radiopharmacies. (**12VAC5-481-570**)
- Distribution of radiochemicals to medical use licensees. (**12VAC5-481-570, 12VAC5-481-1900, 12VAC5-481-1920, 12VAC5-481-1950**)
- Preparation and distribute radioactive drugs to medical use licensees. (**12VAC5-481-480, 12VAC5-481-1900, 12VAC5-481-1920, 12VAC5-481-1950**)
- Redistribution of sealed sources to medical use licensees. (**12VAC5-481-480, 12VAC5-481-1830, 12VAC5-481-2010, 12VAC5-481-2020**)
- Redistribution for in vitro, clinical or laboratory testing to general licensees. (**12VAC5-481-430, 12VAC5-481-480**)
- Manufacture of C-14 Urea capsule; radioactive drug for human diagnostic use to persons exempt from licensing. (**12VAC5-481-400**)
- Receive pharmacy originated radioactive waste from customers. (VDH license)
- Perform leak tests and instrument calibration. (VDH license)

Part 4: Financial Assurance and Recordkeeping for Decommissioning

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

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

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

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

The requirements for financial assurance are specific to the types and quantities of radioactive material authorized on a license. Most commercial radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements, because the vast majority of radioactive materials they possess and redistribute do not have half-lives greater than 120 days and the total inventory of licensed materials with half-lives greater than 120 days do not exceed the thresholds in **12VAC5-481-450 C**.

Applicants requesting more than one radionuclide may determine whether financial assurance for decommissioning is required by calculating, for each radionuclide with a half-life greater than 120 days possessed, the ratio between the activity possessed, in curies, and the radionuclide's threshold activity requiring financial assurance, in curies. If the sum of such ratios for all of the radionuclides possessed exceeds 1 (i.e., 'unity'), then applicants must submit evidence of financial assurance for decommissioning.

The same rule also requires that licensees maintain records important to decommissioning in an identified location. All commercial nuclear pharmacy licensees need to maintain records of structures and equipment where radioactive material was used or stored. As-built drawings with modifications of structures and equipment shown as appropriate fulfill this requirement. If drawings are not available, licensees shall substitute appropriate records (e.g., a sketch of the room or building or a narrative description of the area) concerning the specific areas and locations. If no records exist regarding structures and equipment where radioactive materials were used or stored, licensees shall make all reasonable efforts to create such records based upon historical information (e.g. employee recollections). In addition, if radiopharmacy licensees have experienced unusual occurrences (e.g., incidents that involve spread of contamination, leaking sources), they also need to maintain records about contamination that remains after cleanup or that may have spread to inaccessible areas.

For radiopharmacy licensees whose contamination incidents did not involve radioactive materials with half-lives exceeding 120 days and whose sealed sources have never leaked, acceptable records important to decommissioning are sketches or written descriptions of the specific locations where radioactive material was used or stored.

Note: If financial assurance is required, submit the documentation required under **12VAC5-481-450 C**. NRC Regulatory Guide 3.66, 'Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72', contains approved wording for each of the mechanisms authorized by the rule to guarantee or secure funds except for the Statement of Intent for Government licensees. This document is available at the NRC website, www.nrc.gov, or from VDH upon request.

Note: Licensees must transfer records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with **12VAC5-481-500** or to VDH before the license is terminated.

References: To obtain copies of NRC Regulatory Guide 3.66, 'Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72', and Policy & Guidance Directive (P&GD) FC 90-2, Revision 1, 'Standard Review Plan for Evaluating Compliance with Decommissioning Requirements' visit the NRC's website at www.nrc.gov.

Item 10: Distribution and Redistribution of Licensed Material

Rule: 12VAC5-481-430, 12VAC5-481-440, 12VAC5-481-480, 12VAC5-481-570, 12VAC5-481-850, 12VAC5-481-880, 12VAC5-481-2980

Criteria: The applicant must specify the radioactive material it intends to distribute and redistribute.

Discussion: Radiochemicals are those materials that either require further manipulation to be suitable for human use or are not intended for human use. Examples include raw materials received from a non-**12VAC5-481-480** supplier (chemical grade materials). Radioactive drugs are those materials suitable for human use (e.g., monoclonal antibodies and technetium-99m-tagged red blood cells) and radiopharmaceuticals. However, the terms, 'radiopharmaceutical' and 'radioactive drug' will be used interchangeably in this guidance document and reference to one is not meant to exclude the other.

Distribution activities are normally classified as either 'distribution' or 'redistribution'. 'Distribution' applies to those radioactive drugs and radiochemicals initially prepared by the pharmacy. 'Redistribution' refers to those materials received from another person, authorized pursuant to **12VAC5-481-480**, depending on the product distributed, i.e., *in vitro* kits, other radiopharmaceuticals, or sealed sources for medical use, respectively. The distribution of radioactive materials to other persons requires specific approval from VDH, either by **12VAC5-481 'Virginia Radiation Protection Regulations'** or by a license authorizing the activity. The initial distribution of radioactive drugs for medical use must be prepared by a person licensed pursuant to **12VAC5-481-480**.

The redistribution of *in vitro* kits and sealed sources containing radioactive material for medical use is authorized pursuant to **12VAC5-481-480**, respectively, provided that the materials are not repackaged and the labels are not altered. The *in vitro* kits and sealed sources for medical use intended for redistribution must be initially distributed by a person licensed pursuant to **12VAC5-481-480**, respectively. The transfer of radioactive materials for non-medical use, including radiochemicals, and sealed calibration and reference sources, is authorized pursuant to **12VAC5-481-570**.

All radioactive material listed above shall be distributed only to persons authorized by VDH, the NRC, or another Agreement State license to receive such materials or by a general license (**12VAC5-481-430 G)** to receive *in vitro* test materials.

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

Item 11: Preparation of Radiopharmaceuticals

Rule: 12VAC5-481-450, 12VAC5-481-480

Criteria: The preparation of radiopharmaceuticals for commercial distribution to medical users requires specific authorization.

Discussion: The bulk of radiopharmacy activities involve the preparation of radiopharmaceuticals for commercial distribution to medical users.

Item 12: Service Activities

Rule: 12VAC5-481-450, 12VAC5-481-480, 12VAC5-481-500

Criteria: The applicant must specify the radiation protection services it intends to provide to other licensees (e.g., customers), if the service involves the applicant's possession of licensed material (calibration sources and leak test samples).

Discussion: If the applicant intends to provide radiation protection services to customers, the services must be described. Typically these services include instrument calibration and sealed source leak testing. Specific guidance regarding requests to provide service activities is included in NUREG-1556, Volume 18, 'Program-Specific Guidance About Service Provider Licenses' which can be accessed on the NRC's website www.nrc.gov.

Item 13: Facilities and Equipment

Part 1: Facilities and Equipment

Rule: 12VAC5-481-10, 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-480, 12VAC5-481-520, 12VAC5-481-530, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-780, 12VAC5-481-790, 12VAC5-481-840, 12VAC5-481-850, 12VAC5-481-860, 12VAC5-481-990, 12VAC5-481-2270

Criteria: Radiopharmacies must demonstrate that they are a pharmacy. Facilities and equipment must be adequate to protect health and minimize danger to life or property, minimize the likelihood of contamination, and keep exposures to workers and the public ALARA.

Discussion: Applicants must demonstrate that they are a pharmacy by submitting evidence that they are a licensed as a pharmacy by the Virginia Board of Pharmacy. If the license has not been issued by the Virginia Board of Pharmacy at the time of application, the applicant may provide it at a later date, but prior to license issuance from VDH.

Applicants must provide the agency with documentation demonstrating that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and their employees. The facilities and equipment must also keep exposures to radiation and radioactive materials ALARA and minimize the risks from the uses of the types and quantities of radioactive materials. The applicant should provide clear delineations between its restricted and unrestricted areas through the use of barriers, postings, and worker instructions.

Applicants may delay completing facilities and acquiring equipment until after the application review is completed, in case changes are required as a result of the application review. This also ensures the

adequacy of the facilities and equipment before the applicant makes a significant financial commitment. In all cases, the applicant cannot possess or use licensed material until after the facilities are approved, equipment is procured, and the license is issued.

Applicants are reminded that records important to decommissioning are required to be maintained in an identifiable location. For further information, see **Item 9, Part 4**.

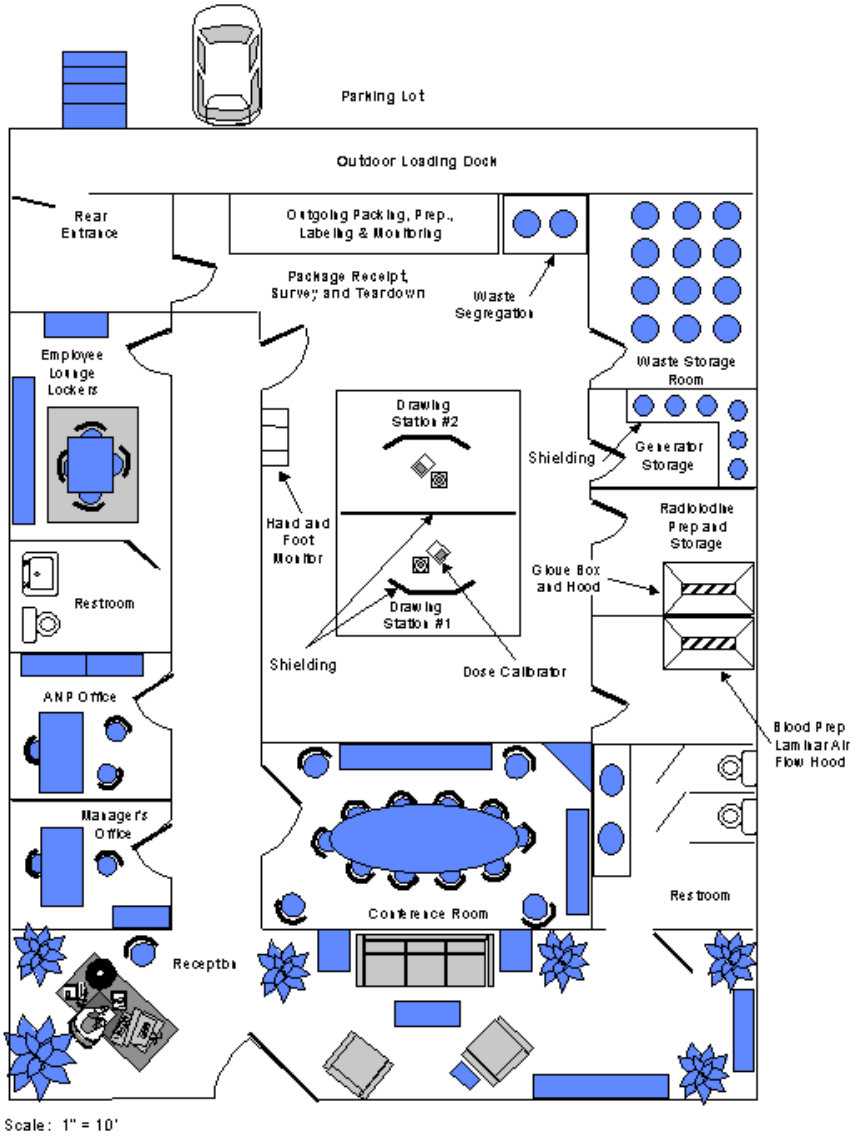


Figure 1. Typical Facility Diagram.

Part 2: Termination of Activities

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

Criteria: The licensee must do the following:

- Notify the agency, in writing, within 60 days of:
  - The expiration of its license;

- A decision to permanently cease licensed activity at the entire site or in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to VDH requirements;
- No principal activities have been conducted at the entire site under the license for a period of 24 months;
- No principal activities have been conducted for a period of 24 months in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to VDH requirements.

- Submit a decommissioning plan, if required by **12VAC5-481-510;**
- Decommissioning, as required by **12VAC5-481-510 & 12VAC5-481-1161;**
- Submit to the agency, a completed VDH form 'Certificate of Disposition of Materials' (**Appendix B**) and demonstrate that the premises are suitable for release for unrestricted use (e.g. results of final survey); and
- Before a license is terminated, send the records important to decommissioning to the agency as required by **12VAC5-481-571**. If licensed activities are transferred or assigned in accordance with **12VAC5-481-500**, transfer records important to decommissioning to the new licensee.

Discussion: For guidance on the disposition of licensed material, see the section on 'Waste Management'. For guidance on decommissioning records, see the section under 'Radioactive Materials' on 'Financial Assurance and Recordkeeping for Decommissioning'.

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

Item 14: Radiation Safety Program

Item 14.1: Audit Program

Rule: 12VAC5-481-480, 12VAC5-481-630, 12VAC5-481-990

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

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

Discussion: Appendix I contain a suggested audit program that is specific to commercial radiopharmacies and is acceptable to the agency. All areas indicated in **Appendix I** may not be applicable to every licensee and all items may not need to be addressed during each audit.

Currently, the agency's emphasis during inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of the radiopharmacy to observe whether radiation safety procedures are being followed, etc.

It is essential that once identified, problems be corrected comprehensively and in a timely manner; NRC Information Notice (IN) 96-28, 'Suggested Guidance Relating to Development and Implementation of

Corrective Action' provides guidance on this subject. The agency will review the licensee's audit results and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. If violations are identified by the licensee and these steps are taken, the agency can exercise discretion and may elect not to cite a violation. The agency's goal is to encourage prompt identification and prompt, comprehensive correction of violations and deficiencies.

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

References: NRC NUREG – 1600, IN 96-28, and IP 87117 are available electronically at http://www.nrc.gov.

Item 14.2: Radiation Monitoring Instruments

Rule: 12VAC5-481-450, 12VAC5-481-480, 12VAC5-481-630, 12VAC5-481-740, 12VAC5-481-750, 12VAC5-481-900, 12VAC5-481-930, 12VAC5-481-990, 12VAC5-481-1000

Criteria: Licensees must possess radiation monitoring instruments to evaluate possible radiation hazards that may be present. Instruments used for quantitative radiation measurements must be calibrated periodically for the radiation measured.

Discussion: Licensees must possess calibrated radiation detection/measurement instruments to perform, as necessary, the following:

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

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

- Portable or stationary count rate meters;
- Portable or stationary dose rate or exposure rate meters;
- Single or multichannel analyzers;
- Liquid Scintillation Counters (LSC);
- Gamma counters;
- Proportional counters;
- Solid state detectors; and
- Hand and foot contamination monitors.

The choice of instrument should be appropriate for the type of radiation to be measured and for the type of measurement to be taken (count rate, dose rate, etc.). Radiopharmacies typically use a broad energy range of gamma and beta radiation emitters and need to use radiation detectors appropriate for those

energies. Applicants should discuss the types of instruments to be used for each type of survey to be performed and the availability of a sufficient quantity of these instruments at their facility.

Instrument calibrations may be performed by the pharmacy or by another person specifically authorized by VDH, the NRC, or another Agreement State to perform that function. If the pharmacy utilizes the services of another person for instrument calibration, the pharmacy should ensure that person has been authorized by VDH, the NRC, or another Agreement State to perform that activity**. Appendix J** provides information about instrument specifications and model calibration procedures.

Note: If the applicant intends to provide radiation protection services, including calibration of survey meters, to customers, the applicant must apply for a service license from VDH.

Item 14.3: Material Receipt and Accountability

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-480, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-740, 12VAC5-481-840, 12VAC5-481-880, 12VAC5-481-900, 12VAC5-481-910, 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1150, 12VAC5-481-1840, 12VAC5-481-3100

Criteria: Licensees must do the following:

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

Discussion: Radioactive materials must be tracked from ‘cradle to grave’ in order to ensure accountability, identify when licensed material could be lost, stolen, or misplaced, and ensure that possession limits listed on the license are not exceeded. Licensees exercise control over radioactive material accountability by including the following items (as applicable) in their radiation protection program:

- Physical inventories of sealed sources at intervals not to exceed 6 months;
- Ordering and receiving licensed material;
- Package opening;
- Maintaining material inventory within license possession limits;
- Transfer of material, including distribution;
- Disposal of material; and
- Use records.

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

Licensees are required to develop, implement, and maintain written procedures for safely opening packages in accordance with **12VAC5-481-900**. Some packages may require special procedures that take into consideration the type, quantity, or half-life of the nuclide being delivered.

A model procedure for safely opening packages containing licensed materials is included in **Appendix P**.

12VAC5-481-900 states the requirements for monitoring packages containing licensed material. These requirements are described in **Table 3**, below.

Table 3. Package Monitoring Requirements

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

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

12VAC5-481-900 requires that the licensee immediately notify the final delivery carrier and VDH when removable radioactive surface contamination exceeds the limit of 22 disintegrations per minute per square centimeter (dpm/cm^2) averaged over 300 cm^2 (6600 dpm/300 cm^2); or external radiation levels exceed 2.0 mSv/hr (200 mrem/hr) at the surface.

Note: Additional information on DOT regulations is contained in this VAREG in **Item 14.12** and **Appendix M**.

Licensees must secure and control licensed material and should have a means of promptly detecting losses of radioactive material. **12VAC5-481-840** requires licensees to secure radioactive materials from unauthorized removal or access while in storage and to control and maintain constant surveillance over radioactive material that is not in storage.

Licenses will normally contain specific conditions requiring the licensee to perform inventories and leak tests of sealed sources every six months. Since the leak tests require an individual to locate and work with the sealed source, records of leak tests may be used as part of an inventory and accountability program. Sources in storage that are used infrequently may not require leak testing; however, the inventory must still be performed at the specified interval.

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

Table 4 list the types and retention times for the records of receipt, use, transfer, and disposal (as waste) of all radioactive material the applicant must maintain. Other records such as transfer records could be linked to radioactive material inventory records.

Table 4. Record Maintenance

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

Maintain inventory records that contain the following types of information:

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

See **Item 15** on 'Waste Disposal and Transfer' for additional information.

Note: Information about locations where licensed material is used or stored are among the records important to decommissioning and required by **12VAC5-481-450 C**. See **Item 9, Part Four**.

Item 14.4: Occupational Dosimetry

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

Criteria: Applicants must do either of the following:

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

OR

- Maintain, for inspection by the agency, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits as shown in **Table 5**.

Table 5: Occupational Dose Limits for Adults

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

Discussion: The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose (prospective evaluation). When performing the prospective evaluation, only a dose that could be received at the facilities of the applicant or licensee performing the evaluation needs to be considered. These estimates can be based on any combination of work location radiation monitoring, survey results, monitoring results of individuals in similar work situations, or other estimates to produce a 'best estimate' of the actual dose received. For individuals who have received doses at other facilities in the current year, the previous dose need not be considered in the prospective evaluation if monitoring was not required at the other facilities. This evaluation need not be made for every individual; evaluations can be made for employees with similar job functions or work areas. Further guidance on evaluating the need to provide monitoring is provided in NRC Regulatory Guide 8.34, 'Monitoring Criteria and Methods to Calculate Occupational Doses'.

If the prospective evaluation shows that an individual's dose is not likely to exceed 10% of any applicable regulatory limit, the individual is not required to be monitored for radiation exposure and there are no recordkeeping or reporting requirements for doses received by that individual. If the prospective dose evaluation shows that the individual is likely to exceed 10% of an applicable limit, monitoring is required.

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

Internal exposure monitoring is required for:

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

If an individual is likely to receive in 1 year a dose greater than 10% of any applicable limit, monitoring for occupational exposure is required. ANPs and radiopharmacy technologists are generally likely to

receive 10% of the limits for occupational dose. Most radiopharmacies provide these employees with whole body and extremity monitors.

Note: Total Effective Dose Equivalent (TEDE) = Deep Dose from External Exposure + Dose from Internally Deposited Radionuclides

When personnel monitoring is needed, most licensees use either film badges or optically stimulated luminescence dosimeters (OSL) that are supplied by a processor holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP). Under **12VAC5-481-750**, licensees must verify that the processor is accredited by NVLAP for the type of radiation for which monitoring will be performed. Consult the NVLAP-accredited processor for its recommendations for exchange frequency and proper use.

The types and quantities of radioactive material used at most commercial radiopharmacies provide a reasonable possibility for an internal intake by ANPs and radiopharmacy technologists. Uses such as preparing radioiodine capsules from liquid solutions and opening and dispensing from vials containing millicurie quantities of radioiodine and other isotopes require particular caution. Precautionary measures for personnel to follow during iodine capsule preparation should involve the use of a fume hood and glove box or shoulder length gloves (see **Appendix Q** for additional guidance on precautionary measures). To monitor internal exposure from such operations, most pharmacies institute a routine bioassay program to periodically monitor these workers.

A program for performing thyroid uptake bioassay measurements should include adequate equipment to perform bioassay measurements, procedures for calibrating the equipment, including factors necessary to convert counts per minute into becquerel or microcurie units and should address the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue). Thyroid bioassay procedures should also specify the interval between bioassays, action levels, and the actions to be taken at those levels. Generally, thyroid uptake bioassay measurements at radiopharmacies are performed weekly for those workers who routinely handle radioiodine or are in the immediate vicinity when radioiodine is being handled. For guidance on developing bioassay programs and determination of internal occupational dose and summation of occupational dose, refer to NRC Regulatory Guide 8.9, Revision 1, ‘Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program’, NRC Regulatory Guide 8.34, ‘Monitoring Criteria and Methods to Calculate Occupational Doses’, , and NRC NUREG - 1400, ‘Air Sampling in the Workplace’.

Note*:* Some licensees choose to monitor their workers for reasons other than compliance with VDH requirements (e.g., in response to worker requests).

References: National Institute of Standards and Technology (NIST) Publication 810, ‘National Voluntary Laboratory Accreditation Program Directory’, is published annually and is available electronically at http://ts.nist.gov/nvlap. NIST Publication 810 can be purchased from GPO, whose URL is http://www.gpo.gov. ANSI N322 may be ordered electronically at http://www.ansi.org or by writing to ANSI, 1430 Broadway, New York, NY 10018. NRC Regulatory Guide 8.7, Revision 1, ‘Instructions for Recording and Reporting Occupational Radiation Exposure Data’,; NRC Regulatory Guide 8.9, Revision 1, ‘Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program’; NRC Regulatory Guide 8.34, ‘Monitoring Criteria and Methods to Calculate Occupational Radiation Doses’, and NRC NUREG - 1400, ‘Air Sampling in the Workplace’, dated September 1993 can be obtained from the NRC website at www.nrc.gov. Contact VDH Radioactive Materials Program if you have questions.

Item 14.5: Public Dose

Rule:. 12VAC5-481-10, 12VAC5-481-630, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-840, 12VAC5-481-1050, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-3080

Criteria: Licensees must do the following:

- Ensure that radioactive material will be used, transported, stored, and disposed of in such a way that members of the public will not receive more than 1 mSv (100 mrem) (TEDE) in one year from licensed activities;
- Ensure that air emissions of radioactive material to the environment will not result in exposures to individual members of the public in excess of 0.1 mSv (10 mrem) (TEDE) in one year from those emissions;
- Ensure that the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour, from licensed operations;
- Prevent unauthorized access, removal, or use of radioactive material.

Discussion: Public dose is defined in **12VAC5-481-10** means "*the dose received by a member of the public from exposure to sources of radiation released by the licensee or registrant, or to any other sources of radiation under the control of the licensee*." Public dose excludes doses received from background radiation, sanitary sewerage discharges from licensees, and from medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individual's assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) the individual is in when the dose is received. For guidance about accepted methodologies for determining dose to members of public, please refer to **Appendix K**.

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

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

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

Licensees should design a monitoring program to ensure compliance with **12VAC5-481-630** and **12VAC5-481-730**. The extent and frequency of monitoring will depend upon each licensee's needs. For additional guidance regarding monitoring of effluents, refer to **Item 14.7**.

During agency inspections, licensees must be able to provide documentation demonstrating, by measurement or calculation, that the TEDE to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit and the dose constraint. See **Appendix K** for examples of methods to demonstrate compliance.

Item 14.6: Safe Use of Radionuclides and Emergency Procedures

Rule: 12VAC5-481-480, 12VAC5-481-490, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-750, 12VAC5-481-760, 12VAC5-481-840, 12VAC5-481-860, 12VAC5-481-870, 12VAC5-481-880, 12VAC5-481-890, 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-2280

Criteria: Licensees are required to do the following:

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

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

General Safety Procedures

The written procedures should include the following elements:

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

These procedures should include policies for:

- Frequency of personnel monitoring;
- Performing molybdenum-99 breakthrough measurements on each elution from a generator;
- Use of appropriate shielding;
- Frequent glove changes to minimize exposure to the individual and to avoid spread of contamination in the laboratory; and
- Special procedures for higher risk activities, such as use of radioiodine.

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

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

Emergency Procedures

Accidents and emergencies can happen during any operation with radioisotopes, including their receipt, transportation, use, transfer, and disposal. Such incidents can result in contamination or release of material to the environment and unintended radiation exposure to workers and members of the public. In addition, loss or theft of radioactive material, and fires involving radioactive material can adversely affect the safety of personnel and members of the public. Applicants should therefore develop and implement procedures to minimize, to the extent practical, the potential impact of these incidents on personnel, members of the public, and the environment.

Applicants should establish written procedures to handle events ranging from a minor spill to a major accident that may require intervention by outside emergency response personnel. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of staff and the radiation safety officer. In addition, the licensee should develop procedures for routine contacts with its local fire department to inform them of its operations and identify locations of radioactive materials and elevated radiation levels in the event of their response to a fire. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, licensee staff should have a clear understanding of their limitations in an emergency with step-by-step instructions and clear direction of whom to contact. The licensee should establish clear delineation's between minor contamination events, minor spills, and major spills and events.

Emergency spill response materials should be strategically placed in well-marked locations for use by all trained staff. All equipment should be periodically inspected for proper operation and replenished as necessary**. Appendix Q** includes model emergency procedures. Applicants may adopt these procedures or develop their own incorporating the safety features included in these model procedures.

Certain incidents and emergencies require notification of VDH. **Appendix T** provides a listing of major VDH reporting and notification requirements relevant to commercial radiopharmacies.

Item 14.7: Surveys

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

Criteria: Licensees are required to make surveys of potential radiological hazards in their workplace. Records of survey results must be maintained.

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

Surveys are required when it is reasonable under the circumstances to evaluate a radiological hazard and when necessary for the licensee to comply with the appropriate rules. Many different types of surveys

may need to be performed due to the particular use of licensed materials. The most important are as follows:

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment;
- Measurements of radioactive material concentrations in air for areas where radiopharmaceuticals are handled or processed in unsealed form and where operations could expose workers to the inhalation of radioactive material (e.g. radioiodine) or where radioactive material is or could be released to unrestricted areas;
- Bioassays to determine the kinds, quantities or concentrations, and in some cases, the location of radioactive material in the human body. Radioiodine uptake in a worker's thyroid gland is commonly measured by external counting using a specialized thyroid detection probe;
- Surveys of external radiation exposure levels in both restricted and unrestricted areas; and
- Surveys of radiopharmaceutical packages entering (e.g., from suppliers and returns from customers) and departing (e.g., prepared radiopharmaceuticals for shipment to customers).

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect workers from external and internal exposure. Also, the frequency of the survey depends on the type of survey, such as those listed above. **Appendix R** contains a procedure for radiation survey frequencies.

Not all instruments can measure a given type of radiation (e.g. alpha, beta and gamma). The presence of other radiation may interfere with a detector's ability to measure the radiation of interest. The energy of the radiation may not be high enough to penetrate some detector windows and be counted. The correct selection, calibration, and use of radiation detection instruments is an important aspect of any radiation safety program.

12VAC5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation' does not specify limits for surface contamination, but it does specify dose limits for unrestricted areas (2 millirem in any one hour) and posting requirements (5 millirem in any one-hour for "*Radiation Areas*"). Each applicant should propose and justify their removable surface contamination and radiation level action limits that will require action to (1) reduce the contamination or radiation level; or (2) institute additional restrictions on access to the area. See **Table 7** located in **Appendix R** for guidance on surface contamination limits acceptable to VDH.

Undetected Contamination and Loss of Control of Radioactive Material

Due to the large quantities of radioactive material in liquid form often handled by radiopharmacy personnel, there can be a greater potential for radioactive material contamination. Radiation surveys, if properly conducted as outlined in this section, will normally detect contamination before it leaves the licensee's restricted area (e.g., radiopharmceutical preparation and packaging areas). If detected within the restricted area during or shortly following radiopharmaceutical preparation, the licensee can normally complete standard decontamination activities to mitigate the spread of the contamination outside the restricted area.

There have been several instances involving licensees, including radiopharmacies, in which contamination has not been detected (usually due to no survey being done, or else an inadequate survey being performed) and which is inadvertently removed from the restricted area. Typically the contamination has been deposited on an outgoing package containing radioactive material, the skin or clothing of a licensee employee leaving the facility, or both. Once the contamination leaves the licensee's restricted area, control of the radioactive material is lost. At this point the contamination has a high

probability of reaching public locations outside the radiopharmacy including one or more of its customers (e.g., a hospital). Contamination incidents such as this can create public health, regulatory, and public relations problems for licensees. In virtually all cases, the events could have been avoided if licensee personnel had performed an adequate radiation survey to detect the contamination before leaving the restricted area.

References: NRC Information Notice 98-18, 'Recent Contamination Incidences Resulting From Failure to Perform Adequate Surveys,' can be found on the NRC's website www.nrc.gov. Contact VDH Radioactive Materials Program with questions.

Item 14.8: Dose Calibrator and Other Dosage Measuring Equipment

Rule: 12VAC5-481-480, 12VAC5-481-750, 12VAC5-481-880, 12VAC5-481-1800, 12VAC5-481-1820, 12VAC5-481-1850, 12VAC5-481-2070

Criteria: Commercial radiopharmacy licensees must possess and use instrumentation capable of accurately measuring the radioactivity in radioactive drugs.

Discussion: Due to the potential for radiopharmacy errors to adversely affect their customers (medical facilities) and their customers' patients, each dosage of a radioactive drug must be measured prior to transfer to provide high confidence that the correct amount of the radioactive drug is transferred in accordance with the customer's request.

The applicant must have procedures for the use of the instrumentation, including the measurement, by direct measurement or by combination of measurement and calculation, of the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to their transfer for commercial distribution.

These procedures must ensure that the dose calibrator, or other dose measurement system, functions properly. This is accomplished by performing periodic checks and tests prior to first use, followed by checks at specified intervals, and following repairs that could affect system performance. Equipment used to measure dosages that emit gamma, alpha, or beta radiation must be calibrated for the applicable radionuclide being measured. Currently, no alpha-emitting nuclides are used in unsealed form in medicine; therefore, guidance is not provided in this document on the measurement of these radionuclides. For photon-emitters, activity measurement is a fairly straightforward determination; however, for beta-emitters, a correction factor is often necessary to accurately determine the activity. There are inherent technical difficulties to overcome in the determination and application of beta-correction factors. These difficulties include dependence on geometry, lack of an industry standard for materials used in the manufacture of both vials and syringes, and lack of a National Institute of Standards and Technology (NIST) traceable standard for all radionuclides currently in use. If radiopharmacies intend to initially distribute (i.e., measure, prepare, and label) beta-emitting radionuclides, the applicant must provide the calculation to demonstrate its ability to accurately dispense such materials. If the applicant intends to use beta-correction factors supplied by the instrument manufacturer, or other entity, it should include a means for ensuring the accuracy of the supplied factor. If radiopharmacy applicants intend to only redistribute beta-emitting radionuclides that have been previously prepared and distributed by other persons licensed pursuant to **12VAC5-481-480** then the correction factor calculation is not required.

Licensees must assay patient dosages in the same type of vial and geometry as used to determine the correct dose calibrator settings. The use of different vials or syringes may result in measurement errors, for example, due to the variation of bremstrahlung created by interaction between beta particles and the differing dosage containers. Licensees are reminded that beta emitters should be shielded using a low-atomic-numbered material to minimize the production of bremstrahlung, followed by a high-atomic-numbered material thick enough to attenuate the bremstrahlung intensity.

For each dose measurement system, specific periodic tests must be performed, as appropriate, to the system to ensure correct operation. Typically, all systems must be checked each day of use for constancy to ensure continued proper operation of the system. In addition, other appropriate tests may include accuracy (for the range of energies to be measured), linearity (for the range of activities to be measured), and geometry dependence (for the range of volumes and product containers).

The applicant should ensure that it possesses a sufficient number of such instruments to allow for periods when instruments are out of service for repair and calibration.

Appendix O contains a model procedure for dose calibrator testing.

Note: If the applicant intends to provide radiation protection services, including calibration of dose calibrators, to customers, the applicant must apply for a service license from VDH.

Item 14.9: Radioactive Drug Labeling for Distribution

Rule: 12VAC5-481-470, 12VAC5-481-850, 12VAC5-481-880, 12VAC5-481-890

Criteria: The labels affixed to radioactive drugs for distribution must have the required color, symbol, and wording.

Discussion: The licensee must label each ‘transport radiation shield’ to show the radiation symbol as described in **12VAC5-481-880**. The label must also include the words "*CAUTION, RADIOACTIVE MATERIAL*" or "*DANGER, RADIOACTIVE MATERIAL*", the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specified date and time. The phrase ‘transport radiation shield’ refers to the primary shield for the radioactive drug, which may include the syringe, vial, or syringe or vial shield. The ‘transport radiation shield’ should be constructed of material appropriate for the isotope to be transferred for commercial distribution. The ‘transport radiation shield’ does not refer to the outer suitcase, packaging, or other carrying device, even though that barrier may provide some radiation shielding.

The licensee must label each syringe, vial, or other container (e.g., generator or ampule) used to hold radioactive drugs to be transferred for commercial distribution to show the radiation symbol, as described in **12VAC5-481-880**. The label must include the words "*CAUTION, RADIOACTIVE MATERIAL*" or "*DANGER, RADIOACTIVE MATERIAL*", and an identifier that ensures the syringe, vial, or other container can be correlated with the information on the ‘transport radiation shield’ label. The identifier must provide a correlation between the syringe, vial, or other container and the information on the label of its ‘transport radiation shield’. Identifiers may include the prescription number, the name of the radioactive drug or its abbreviation, the name of the patient, or the clinical procedure.

Item 14.10: Radioactive Drug Shielding for Distribution

Rule: 12VAC5-481-480, 12VAC5-481-630, 12VAC5-481-640

Criteria: The shielding provided for each radioactive drug to be distributed must be adequate for safe handling and storage by the pharmacy's customers to maintain occupational exposures ALARA.

Discussion: The applicant must provide appropriate 'transport radiation shields' for the primary container of each radioactive drug that it intends to distribute. The shielding must be adequate for the types and activities of radioactive materials that the applicant intends to distribute. Typically, 'transport radiation shields' used by radiopharmacies have included two-piece, shielded syringe and vial containers (or 'pigs'). Pharmacies have used lead and tungsten shields for gamma-emitting materials and plexiglass inserts for beta-emitters.

As general guidelines, 'transport radiation shields' for Technetium-99m products have ensured surface radiation levels of not more than 0.03 milliSievert per hour (mSv/hr) (3 mrem/hr), due to the ease of shielding the low energy gamma emitted. For Iodine-131, surface dose rates on 'transport radiation shields' have been approved up to 0.5 mSv/hr (50 mrem/hr) for diagnostic dosages and up to 1.5 mSv/hr (150 mrem/hr) for therapeutic dosages. The applicant should select appropriate shielding materials and dimensions to not only ensure that occupational doses are ALARA, but also that the 'transport radiation shield' can be easily handled.

Item 14.11: Leak Test

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

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

Discussion: A licensee will be required to perform leak tests at intervals not to exceed six months unless otherwise approved by VDH, the NRC, or another Agreement State and it is documented in the SSD Registration Sheet. The measurement of the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 becquerels (0.005 microcurie) of radioactivity.

Commercial radiopharmacies may have their sealed sources leak tested by an individual licensed by VDH, the NRC, or another Agreement State to perform leak testing or radiopharmacies may perform leak testing of their own sealed sources. **Appendix L** contains a procedure for performance of leak testing and sample analysis. If the radiopharmacy has its leak testing performed by a licensed leak test provider, the radiopharmacy is expected to take the leak test samples according to the sealed source manufacturer's and the leak test provider's kit instructions and return it to the provider for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking.

Note: If the applicant intends to provide radiation protection services, including leak testing, to customers, the applicant must apply for a service license from VDH.

Item 14.12: Transportation

Rule: 12VAC5-481-100, 12VAC5-481-480, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-2980, 12VAC5-481-2990, 12VAC5-481-3000, 12VAC5-481-3010, 12VAC5-481-3020, 12VAC5-481-3030, 12VAC5-481-3070, 12VAC5-481-3080, 12VAC5-481-3091, 12VAC5-481-3100, 12VAC5-481-3110, 12VAC5-481-3130, 49 CFR Parts 171-178

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

Discussion: The agency inspects and enforces DOT's regulations governing the transport of radioactive materials by VDH's licensees.

The types and quantities of radioactive materials shipped by commercial radiopharmacy licensees will nearly always meet the criteria for shipment in a "*Type A*" package, as defined by the DOT. The requirements for these packages include the provisions for shipping papers, packaging design standards, package marking and labeling, and radiation and contamination level limits. For radiopharmacies who transport their own packages, the packages must be blocked and braced, and shipping papers must be used and located properly in the driver's compartment.

Packaging used by commercial radiopharmacies typically includes military ammunition boxes, 'briefcases', and cardboard/fiberboard boxes. These packages will normally meet the criteria for "*Type A*" quantities, which must meet specified performance standards to demonstrate that they will maintain the integrity of containment and shielding under normal conditions of transport. Such packages will normally withstand minor accident situations and rough handling conditions. The testing criteria for Type A packages are listed in **49 CFR 173.465**. Before offering a Type A package for shipment, the shipper is responsible for ensuring that the package has been tested to meet the criteria for the contents and the configuration to be shipped and maintaining a certificate of testing. Shippers are not required to personally test the packages, but must ensure that the testing was performed before use and maintain a record of the testing.

DOT regulations also require that individuals who perform functions related to the packaging and shipment of radioactive material packages receive training specific to those functions. The training must include a general awareness of DOT requirements, function-specific training for the individuals' duties, and safety training. DOT also specifies the frequency of the training and a record retention requirement for training (see **Item 8**).

An outline of DOT and VDH requirements generally relevant to commercial radiopharmacy operations is included for applicant and licensee reference in **Appendix M**.

References: 'A Review of Department of Transportation Regulations for Transportation of Radioactive Materials', can be obtained be calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4425. The Memorandum of Understanding with DOT on the Transportation of Radioactive Material, is available from NRC.

Item 14.13: Minimization of Contamination

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

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

Discussion: All applicants for new licenses need to consider the importance of designing and operating their facilities to minimize the amount of radioactive contamination generated at the site during its operating lifetime and to minimize the generation of radioactive waste during decontamination. In the case of commercial radiopharmacy applicants, these issues usually do not need to be addressed as a separate item, as they are included in responses to other items of the application.

The bulk of unsealed radioactive material utilized by radiopharmacies have short half-lives (under 120 days). These radionuclides do not pose a source of long-term contamination. Additionally, nearly all radioactive waste generated by radiopharmacies is stored for decay rather than transferred to a radioactive waste disposal facility.

The licensee may possess and redistribute sealed sources that contain radionuclides with long half-lives. These sealed sources have been approved by NRC or another Agreement State and, if used according to the respective SSD Registration Certificate, usually pose little risk of contamination. Leak tests performed at the frequency specified in the SSD Registration Certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and decontaminated, repaired, or disposed of according to VDH requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts.

Item 15: Waste Disposal and Transfer

Item 15.1: Waste Management

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-480, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-720, 12VAC5-481-750, 12VAC5-481-880, 12VAC5-481-900, 12VAC5-481-910, 12VAC5-481-920, 12VAC5-481-930, 12VAC5-481-940, 12VAC5-481-950, 12VAC5-481-960, 12VAC5-481-970, 12VAC5-481-971, 12VAC5-481-1000, 12VAC5-481-1060, 12VAC5-481-1100, 12VAC5-481-1890, 12VAC5-481-2571, 12VAC5-481-2980, 12VAC5-481-3690

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

Discussion: Radioactive waste is normally generated when conducting licensed activities. Such waste may include used or unused radioactive material, and unusable items contaminated with radioactive material (e.g., absorbent paper, gloves, etc). Licensees may not receive radioactive waste from other licensees for processing, storage or disposal, unless specifically authorized to do so by VDH. Commercial radiopharmacies may request to receive certain radioactive waste returned from their customers. For guidance on receiving radioactive waste from customers, refer to the section titled, ‘Returned Wastes from Customers’.

All radioactive waste must be stored in appropriate containers until its disposal and the integrity of the waste containers must be assured. Radioactive waste containers must be appropriately labeled. All radioactive waste must be secured against unauthorized access or removal. VDH requires commercial

radiopharmacy licensees to manage radioactive waste generated at their facilities by one or more of the following methods:

- Decay-in-Storage (DIS);
- Transfer to an authorized recipient; and
- Release into sanitary sewerage.

Licensees may choose any one or more of these methods to dispose of their radioactive waste. Most commercial radiopharmacies dispose of radioactive waste by decay-in-storage because the majority of radioactive materials used by these facilities have short half-lives.

Applicant's programs for management and disposal of radioactive waste should include procedures for handling of waste, safe and secure storage, characterization, minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. **12VAC5-481 'Virginia Radiation Protection Regulations'** requires licensees to maintain all appropriate records of disposal of radioactive waste.

Disposal by Decay-in-Storage (DIS)

VDH permits radioactive materials with half-lives of less than or equal to 120 days to be disposed by DIS. The minimum holding period for decay is ten half-lives of the longest-lived radioisotope in the waste. Applicants should assure that adequate space and facilities are available for the storage of such waste. Procedures for management of waste by DIS should include methods of segregation, surveys prior to disposal, and maintenance of records of disposal.

Licensees can minimize the need for storage space, if radioactive waste is segregated according to physical half-life. Segregation of waste is accomplished by depositing radioisotopes of shorter physical half-lives in containers separate from those used to store radioactive waste with longer physical half-lives. Radioactive waste with shorter half-lives will take less time to decay and thus may be disposed in shorter periods of time, freeing storage space.

Used syringes/needles and vials returned from pharmacy customers (medical facilities) are considered both biohazardous and radioactive waste since these items may be contaminated with the customer's patients' blood or other body fluids. Following completion of decay-in-storage, such waste may be disposed of as biohazardous waste (medical waste) if radiation surveys (performed in a low background area and without any interposed shielding) of the waste at the end of the holding period indicate that radiation levels are indistinguishable from background.

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

- The radioactive material labels on the outer waste barrels/containers will be defaced or removed prior to transfer to waste disposal firm;
- Waste barrels are sealed prior to delivery to the waste disposal firm;
- Waste barrels/containers will be delivered directly from the licensee's facility to a waste disposal firm for disposal;

- Medical waste is incinerated, and not sent to a medical waste landfill; and
- The waste disposal firm is notified that the barrels must not be opened at any point, and for any reason, prior to incineration.

Other pharmacy radioactive waste that has not been returned from customers and has not otherwise come into contact with blood or body fluids should not have a biohazardous component. Following completion of DIS and provided it has been stored separate from radioactive, biohazardous waste and contains no other hazardous components (e.g. needles, hazardous chemicals), such waste may require disposal as ordinary trash if radiation surveys (performed in a low background area and without any interposed shielding) of the waste at the end of the holding period indicate that radiation levels are indistinguishable from background. All radiation labels must be defaced or removed from containers and packages prior to final disposal as ordinary trash. If the decayed waste is compacted, all labels that are visible in the compacted mass must also be defaced or removed.

Records of DIS should include the date when the waste was put in storage for decay, date when ten half-lives of the longest-lived radioisotope have transpired, date of disposal, results of final survey before disposal as ordinary trash and results of the background survey, identification of the instrument used to perform the survey and the signature or initials of the individual performing the survey.

Transfer to an Authorized Recipient

Licensees may transfer radioactive waste to an authorized recipient for disposal. Most commercial radiopharmacies only dispose of radioactive wastes with half-lives greater than 120 days to authorized recipients (e.g., low-level radioactive waste disposal facilities). Since radiopharmacy licensees typically possess small quantities of these materials, the volume of materials disposed in this manner would also be minimal, if any. Currently, radiopharmacies use this system for waste disposal infrequently; therefore, detailed guidance is not provided in this document on the specific requirements related to the transfer of wastes to authorized recipients for disposal.

Release Into Sanitary Sewerage

Licensees may dispose of radioactive waste by release into sanitary sewerage if each of the following conditions are met:

- Material is readily soluble (or is easily dispersible biological material) in water;
- Quantity of licensed material that the licensee releases into the sewer each month averaged over the monthly volume of water released into the sewer does not exceed the concentration specified in **12VAC5-481-3690, Table III**;
- If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit in **12VAC5-481-3690, Table III,** cannot exceed unity; and
- Total quantity of licensed material released into the sanitary sewerage system in a year does not exceed the limits specified in **12VAC5-481-930**.

Licensees are responsible for demonstrating that licensed materials discharged into the sewerage system are, indeed, readily dispersible in water. NRC IN 94-07, ‘Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20’, dated January 1994, provides the criteria for evaluating solubility of liquid waste.

Applicants shall develop and implement procedures to ensure that all releases of radioactive waste into the sanitary sewerage, if any, meet the criteria stated in **12VAC5-481-930**. Licensees are required to maintain accurate records of all releases of radioactive material into the sanitary sewer.

References: NRC Policy and Guidance Directive PG 94-05, 'Updated Guidance on Decay-In-Storage'; NRC Information Notice 94-07, 'Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20'; and NRC Information Notice 84-94, 'Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems Permitted Under 10 CFR 20.203 (now 10 CFR 20.2003)', can be accessed from the NRC's website at http://www.nrc.gov. Contact VDH Radioactive Materials Program with questions.

Item 15.2: Returned Wastes from Customers

Rule: 12VAC5-481-450, 12VAC5-481-480, 12VAC5-481-570, 12VAC5-481-910, 12VAC5-481-2980

Criteria: Commercial radiopharmacies may receive radioactive waste from customers. This radioactive waste is limited to items that originated at the radiopharmacy and that contained (or contain) radioactive material delivered for customer use (e.g., pharmacy supplied syringes and vials and their contents).

Discussion: Commercial radiopharmacy licenses contain a license condition that permits radioactive waste, consisting of pharmacy supplied items, to be received from their customers. The customer may return, and the radiopharmacy may accept for disposal, only items originating at the radiopharmacy that contained or contain radioactive material. This is limited to pharmacy-supplied syringes and vials and their contents. It is not acceptable for customers to return items originating at their facilities that are contaminated with radioactive material supplied by the pharmacy (e.g., gloves, absorbent material, IV tubing, patient contaminated items). If an applicant wishes a broader authorization for radioactive waste retrieval, the applicant must apply for a separate license as a radioactive waste broker under the general provisions of **12VAC5-481-450** and **12VAC5-481-910.**

Radiopharmacy customers, who act as the shipper for returned materials, should be supplied with detailed written instructions on how to properly prepare and package radioactive waste for return to the radiopharmacy. These instructions should clearly indicate that only items that contained or contain radioactive materials supplied by the radiopharmacy may be returned. In addition, these instructions should be adequate to ensure that customers comply with Department of Transportation (DOT) regulations and VDH rule for the packaging and transport of radioactive materials and for the radiation safety of drivers/couriers. Since customers may return unused syringes and vials, which may contain significant quantities of radioactive material, the radiopharmacy should also include in their instructions methods for determining that the activities of radioisotopes returned to the pharmacy are "*Limited Quantities*", or otherwise ensure that customers prepare and offer packages for transport that meet VDH and DOT requirements if the packages contain greater than limited quantities of radioactive material. The radiopharmacy should also have written instructions for pharmacy staff to address pick-up, receipt, and disposal of the returnable radioactive waste. **Appendix S** contains a procedure for return of pharmacy radioactive wastes from customers.

If the pharmacy chooses to take the responsibility to act as the shipper for returned materials, the pharmacy must ensure that its customer follows DOT regulations and VDH rule for the packaging and transport of radioactive materials and for the radiation safety of drivers/couriers in the return process.

Note: Retrieval, receipt, and disposal of pharmacy supplied syringes and vials from customers is authorized via a license condition.

Item 16: License Fees

For a listing of application fees, please see **12VAC5-490**. On VDH form, **'**Application for A Radioactive Material License for Commercial Radiopharmacies**'** (**Appendix A**), enter the fee category and the amount.

Item 17: Certification

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

Note:

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

Appendix A:

VDH Form,
‘Application for a Radioactive Material License for Commercial Radiopharmacies’

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

APPLICATION FOR A NEW RADIOACTIVE MATERIAL LICENSE FOR A COMMERICAL RADIOPHARMACY

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

Instructions: Complete all items. Refer to VAREG "Guidance for Commercial Radiopharmacy." Use supplementary sheets where necessary. Retain one copy and submit original of the entire application to the Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219

APPLICATION TYPE

Item 1 Type Of Application (Check Box)

☐ New License

CONTACT INFORMATION

Item 2 Name And Mailing Address Of Applicant:	**Item 3 Person To Contact Regarding Application:**
, -	
Applicant's Telephone Number (Include Area Code):	**Contact's Telephone Number** (Include Area Code):
( ) - x	( ) - x

LOCATION OF RADIOACTIVE MATERIAL

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

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

Revision 1 August 1, 2012

RADIATION SAFETY OFFICER

Item 5 Radiation Safety Officer (RSO) (Check all that apply and attach evidence of training and experience)

NAME _____ TELEPHONE NUMBER (_____) _____ - _____ x _____
(Include area code)

☐ We will submit an organizational chart describing the management structure, reporting paths, and the flow of authority between executive management and the RSO.

AND EITHER

☐ A copy of the license (VDH, the NRC or an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO, an Authorized Nuclear Pharmacist, or an Authorized User.

OR

☐ A description of the training and experience demonstrating that the proposed RSO is qualified by training and experience as applicable to commercial nuclear pharmacies. Appendix G in VAREG 'Guidance for Commercial Radiopharmacy' should be used in documenting and determining required training and experience.

AUTHORIZED NUCLEAR PHARMACIST

Item 6 Authorized Nuclear Pharmacist (ANP) (Check all that apply and attach evidence of training and experience)

☐ We will provide a copy of the State pharmacy licensure for each pharmacist.

AND ONE OF THE FOLLOWING

☐ We will provide a copy of the license (VDH, the NRC or another Agreement State) on which the individual was specifically named as an ANP.

OR

☐ We will provide a copy of the permit maintained by a broad scope licensee or NRC master material licensee.

OR

☐ We will provide a copy of the certification(s) for the radiopharmacy board(s), and e will provide a written certification, signed by a preceptor ANP, that the training and experience as specified in **12VAC5-481-1770** has been completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

OR

☐ We will provide a description of the training and experience demonstrating that the proposed ANP is qualified by training and experience, and we will provide a written certification, signed by a preceptor ANP, that the training and experience as specified in **12VAC5-481-1770** has been completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

AUTHORIZED USERS

Item 7 Authorized Users (AU) (Check all that apply)

☐ We will provide the individual's name and identify types, quantities, and proposed uses of licensed material.

AND ONE OF THE FOLLOWING

☐ We will provide a copy of the license (VDH, the NRC or another Agreement State) on which the individual was specified as an AU for the types and quantities and proposed uses of licensed materials.

OR

☐ We will provide a copy of the permit maintained by a broad scope licensee or NRC master material licensee that identifies the individual as an AU for the types, quantities, and proposed uses of licensed materials.

OR

☐ We will provide a description of the training and experience demonstrating that the proposed AU is qualified to use the requested licensed materials. Appendix G in VAREG 'Guidance for Commercial Radiopharmacy' may be helpful in describing the training and experience required.

TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Item 8.1 Occupationally Exposed Workers And Ancillary Personnel (Check box if applicable)

☐ We have developed and will implement and maintain written procedures for a training program for each group of workers, including: topics covered; qualifications of the instructors; method of training; method for assessing the success of the training; and the frequency of training and refresher training. (Procedures are attached)

Item 8.2 Personnel Involved In Hazardous Materials Package Preparation And Transport (Check box if applicable)

☐ We have developed and will implement and maintain written procedures for training personnel involved in hazardous materials package preparation and transport that meet the requirements in 49 CFR 172.700, 49 CFR 172.702 AND 49 CFR 172.704, as applicable. (Procedures are attached)

RADIOACTIVE MATERIALS

Item 9 Radioactive Material (Attach additional pages if necessary)

Item 9.1 Radioisotope(s)

Item 9.2 Chemical/Physical Form of radioisotopes requested.

Are open containers of potentially volatile materials (Iodine-131) manipulated at this location?	☐ Yes ☐ No If yes, process and engineering controls must be described.
Are sealed sources used at this location?	☐ Yes ☐ No If yes, please fill out Items 9.3 – 9.5, otherwise proceed to Item 9.6

Item 9.3 Sealed Source Manufacturer or Distributor and Model Number of sealed sources requested.

Item 9.4 Device Manufacturer or Distributor and Model Number of devices requested.

Is Depleted Uranium used as a shielding material?	☐ Yes ☐ No If yes, specify the total amount (in Kilograms)

Item 9.5 Maximum possession limit for each radioisotope requested.

Item 9.6 Proposed use for each radioisotope requested.

PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

Item 10 Distribution And Redistribution Of Licensed Materials

Item 10.1 Radiopharmaceuticals (Check both boxes)

☐ We will confirm that radiopharmaceuticals will be prepared under the supervision of an ANP or will be obtained from a supplier authorized pursuant to **12VAC5-481-480 I**, or under equivalent NRC or other Agreement State requirements;

AND

☐ We will describe all licensed material to be distributed or redistributed.

Item 10.2 Generators (Check all boxes if using generators)

☐ Confirm that the generators will be obtained from a manufacturer licensed pursuant to **12VAC5-481-480 I**, or under equivalent NRC or other Agreement State requirements.

AND

☐ Confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging.

Item 10.3 Redistribution Of Generators (Check all boxes if redistributing generators)

☐ We will submit a description of the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of migration of radioactive fluids out of the generator during transport.

AND

☐ Confirm that the manufacturer's packaging and labeling will not be altered.

AND

☐ Confirm that the generator will not be distributed beyond the expiration date shown on the generator label.

AND

☐ Confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator.

AND

☐ Confirm that only generators used in accordance with the manufacturer's instructions will be redistributed.

Note: Although redistribution of used generators may be authorized by VDH, VDH approval does not relieve the licensee from complying with applicable FDA or other Federal or state requirements.

Item 10.4 Redistribution Of Sealed Sources – For Brachytherapy Or Diagnosis (Check all boxes if redistributing sealed sources, for brachytherapy or diagnosis)

☐ Confirm that the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued in pursuant to **12VAC5-481-480 J**, or under equivalent NRC or other Agreement State requirements.

AND

☐ Confirm that the manufacturer's packaging, labeling and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

Item 10.5 Redistribution Of Calibration And Reference Sealed Sources (Check all boxes if redistributing calibration and reference sealed sources)

☐ Confirm that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a person licensed pursuant to **12VAC5-481-480 J**, or under equivalent NRC or other Agreement State requirements, to initially distribute such sources.

AND

☐ Confirm that the manufacturer's labeling and packaging will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

Item 10.6 Redistribution Of Prepackaged Units For In-Vitro Tests (Check box if redistributing prepackaged units for In-vitro tests)

☐ Confirm that the prepackaged units for in-vitro tests to be redistributed will have been obtained from a manufacturer licensed to distribute the prepackaged units for in-vitro tests pursuant to **12VAC5-481-480 G**, or under equivalent NRC or other Agreement State requirements.

Item 10.7 Redistribution To General Licensee (Check all boxes if redistributing to a general licensee)

☐ Confirm that the manufacturer's packaging and labeling of the prepackaged units for in-vitro tests will not be altered in any way.

AND

☐ Confirm that each redistributed prepackaged unit for in-vitro tests will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees.

Item 10.8 Redistribution To Specific License (Check box)

☐ Confirm that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed prepackaged units for in-vitro test will NOT reference general licenses, exempt quantities, or VDH, NRC, or Agreement State regulations that authorize a general license.

PREPARATION OF RADIOPHARMACEUTICALS

Item 11 Preparation Of Radiopharmaceuticals (Check box)

☐ We will attach a document that indicates the types of radiopharmaceuticals preparation activities we intend to perform (e.g.; compounding of Iodine-131 capsules, radioiodination, and technetium-99m kit preparation). (Document is attached)

SERVICE ACTIVITIES

Item 12 Service Activities (Check box)

☐ We will submit specific procedures for all radiation protection services that we intend to provide to other licensees (e.g. customers). (Procedures are attached)

FACILITIES AND EQUIPMENT

Item 13 Facilities And Equipment (Check boxes and attach diagram.)

☐ We will provide copies of a license from the State Board of Pharmacy; or evidence that we are operating as a nuclear pharmacy within a state medical institution.

Note: There may be a jurisdiction that does not recognize the practice of commercial radiopharmacy. In these cases, the applicant must submit evidence that it is registered or licensed with the FDA as a drug manufacturer.

AND

☐ We will provide a description of the facilities and equipment to be made available where radioactive material will be used. A diagram should provide be submitted showing the entire facility and identify activities conducted in all contiguous areas surrounding the facility. Diagrams should be drawn to specified scale, or dimensions should be indicated. For additional information refer to VAREG 'Guidance for Commercial Radiopharmacy'. (Description is attached)

RADIATION SAFETY PROGRAM

Item 14 Radiation Safety Program

Item 14.1 Audit Program

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

Item 14.2 Radiation Monitoring Instruments (Check one box)

☐ We will use equipment that meets the radiation monitoring instrument specifications and implement the survey meter calibration program published in Appendix J of VAREG 'Guidance for Commercial Radiopharmacy'.

OR

☐ We will use equipment that meets the radiation monitoring instrument specifications published in Appendix J of VAREG 'Guidance for Commercial Radiopharmacy', and instruments will be calibrated by licensees authorized by VDH, the NRC or another Agreement State.

OR

☐ We will provide a description of alternative equipment to be used for radiation monitoring and alternative procedures for the calibration of radiation monitoring equipment. (Procedures are Attached)

Item 14.3 Material Receipt And Accountability (Check all boxes)

☐ We have developed, and will implement and maintain, written procedures for safely opening packages that meet the requirements in **12VAC5-481-900**.

AND

☐ We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed 6 months.

AND

☐ We have developed, and will implement and maintain written procedures for radioactive material accountability and control to ensure that:

1. License possession limits are not exceeded;
2. Radioactive material in storage is secured from unauthorized access or removal;
3. Radioactive material not in storage is maintained under constant surveillance and control; and
4. Records of receipt, transfer, and disposal of licensed material are maintained.

(Procedures are attached)

Item 14.4 Occupational Dosimetry (Check all that apply)

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

AND / OR

☐ We will maintain for inspection by the agency, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in **12VAC5-481-640**.

Item 14.5 Public Dose

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

Item 14.6 Safe Use Of Radionuclidies And Emergency Procedures (Check box)

☐ We will develop, implement and maintain safe use of radionuclides and emergency procedures that meets the criteria in the section titled 'Safe Use of Radionuclides and Emergency Procedures' in VAREG 'Guidance for Commercial Radiopharmacy'. (Procedures are Attached)

Item 14.7 Surveys (Check one box)

☐ We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix R of VAREG 'Guidance for Commercial Radiopharmacy'.

OR

☐ We will develop, implement and maintain written procedures for a survey program that specifies the performance of radiation and contamination level surveys in restricted and unrestricted areas, personnel contamination monitoring, action levels, and the frequencies and records maintenance of those surveys and monitoring that meet the requirements in **12VAC5-481-100, 12VAC5-481-750 and 12VAC5-481-1000**. (Procedures attached)

Item 14.8 Dose Calibrator And Other Dosage Measuring Equipment (Check all that apply)

☐ We will describe the types of systems (measurement or combination of measurement and calculation) that we intend to use for the measurement of alpha-beta, and photon-emitting radioactive drugs.

AND

☐ We will develop, implement and maintain a written procedure for the performance of dose measurement system checks and tests that meet the requirements in **12VAC5-481-480 I**. (Procedures are attached)

AND EITHER

☐ We will provide, if applicable, a sample calculation for determining beta-correction factors for dose calibrators with ionization chambers.

OR

☐ We will include, if applicable, a means for ensuring the accuracy of beta-correction factors supplied by the instrument manufacturer, or other entity.

Item 14.9 Radioactive Drug Labeling For Distribution (Check both boxes)

☐ We will describe all labels, indicating the colors to be used, that will accompany the products and describe where each label is placed (e.g. on the "transport radiation shield" or the container used to hold the radioactive drug); (Description is attached)

AND

☐ Agree to affix the required labels to all "transport radiation shields" and each container used to hold the radioactive drugs.

Item 14.10 Radioactive Drug Shielding For Distribution (Check box)

☐ For each drug to be distributed, we will (except for products intended for redistribution without manipulation and in the manufacturer's original shipping package):

- Indicate the radionuclide and the maximum activity for each type of container (e.g. vial, syringe);
- Describe the type and thickness of the "transport radiation shield" provided for each type of container; and
- Indicate the maximum radiation level to be expected at the surface of each "transport radiation shield" when the radioactive drug container is filled with the maximum activity.

NOTE: It is not acceptable to State that the applicant will comply with DOT regulations. The dose rate limits that DOT imposes apply to the surface of the package, not the surface of the "Transport Radiation Shield."

Item 14.11 Leak Test (Check one box)

☐ Leak tests will be performed by an organization authorized by VDH, the NRC or another Agreement State to provide leak testing services to other licensees; or by using a leak test kit supplied by an organization licensed by VDH, the NRC or another Agreement State to provide leak test kits to other licensees according to kit supplier's instructions.

License number of organization authorized to perform or analyze leak test (Specify whether VDH, NRC, or another Agreement State):

Organization Name: _____ License Number: _____
Issuing Agency: _____

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

OR

☐ We will perform our own leak testing and sample analysis. We will follow the procedures in Appendix L of VAREG 'Guidance for Commercial Radiopharmacy'.

OR

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

WASTE DISPOSAL AND TRANSFER

Item 15 Waste Disposal And Transfer

Item 15.1 Waste Management (Check box)

☐ We will develop, implement and maintain procedures for waste collection, storage and disposal by any of the authorized methods described in the section titled 'Waste Management' of VAREG 'Guidance for Commercial Radiopharmacy'. We will contact VDH for guidance to obtain approval of any method(s) of waste disposal other than those discussed in the section titled 'Waste Management' of VAREG 'Guidance for Commercial Radiopharmacy'. (Procedures are attached)

Item 15.2 Returned Waste From Customers (Check one box)

☐ We will follow the procedures for returned waste from customers in Appendix S of VAREG 'Guidance for Commercial Radiopharmacy'.

OR

☐ We will develop, implement and maintain procedures for returned waste from customers, that will meet the criteria in the section titled 'Returned Waste from Customers' in VAREG 'Guidance for Commercial Radiopharmacy'. (Procedures are attached)

SPECIFIC LICENSE FEE

Item 16 License Fees (Refer to **12VAC5-490**)

License fee enclosed

☐ Yes Amount Enclosed $_____

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

Item 17

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

SIGNATURE - Applicant Or Authorized Individual	Date signed

Print Name and Title of above signatory

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

APPLICATION FOR RENEWAL OF A RADIOACTIVE MATERIAL LICENSE FOR A COMMERICAL RADIOPHARMACY

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

Instructions: Complete all items. Refer to VAREG "Guidance for Commercial Radiopharmacy." Use supplementary sheets where necessary. Retain one copy and submit original of the entire application to the Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219

APPLICATION TYPE

Item 1 Type Of Application (Check Box)

☐ New License

CONTACT INFORMATION

Item 2 Name And Mailing Address Of Applicant:	**Item 3 Person To Contact Regarding Application:**
, -	
Applicant's Telephone Number (Include Area Code): ( ) - x	**Contact's Telephone Number** (Include Area Code): ( ) - x

LOCATION OF RADIOACTIVE MATERIAL

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

☐ as listed on current license
OR
☐ as listed on current license and please add the listed additional locations
OR
☐ see provided information for current information

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

Revision 1 August 1, 2012

RADIATION SAFETY OFFICER

Item 5 Radiation Safety Officer (RSO) (Check all that apply and attach evidence of training and experience)

☐ As listed on the current license

OR

☐ See attached for proposed Radiation Safety Officer

NAME _____ TELEPHONE NUMBER (_____) _____ - _____ x _____
(Include area code)

AUTHORIZED NUCLEAR PHARMACIST

Item 6 Authorized Nuclear Pharmacist (ANP) (Check all that apply and attach evidence of training and experience)

☐ As listed on the current license

OR

☐ As listed on the current license and see attached for proposed Authorized Nuclear Pharmacist.

OR

☐ See attached for proposed Authorized Nuclear Pharmacist.

AUTHORIZED USERS

Item 7 Authorized Users (AU) (Check all that apply)

☐ As listed on the current license

OR

☐ As listed on the current license and see attached for additional proposed Authorized Users.

OR

☐ See attached for proposed Authorized Users.

TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Item 8.1 Occupationally Exposed Workers And Ancillary Personnel (Check box if applicable)

☐ We have developed and will implement and maintain written procedures for a training program for each group of workers, including: topics covered; qualifications of the instructors; method of training; method for assessing the success of the training; and the frequency of training and refresher training. (Procedures are attached)

Item 8.2 Personnel Involved In Hazardous Materials Package Preparation And Transport (Check box if applicable)

☐ We have developed and will implement and maintain written procedures for training personnel involved in hazardous materials package preparation and transport that meet the requirements in 49 CFR 172.700, 49 CFR 172.702 AND 49 CFR 172.704, as applicable. (Procedures are attached)

RADIOACTIVE MATERIALS

Item 9 Radioactive Material (Attach additional pages if necessary)

☐ As listed on the current license

OR

☐ As listed on the current license and see attached for additional material.

OR

☐ See attached for material requested.

Is Depleted Uranium used as a shielding material? ☐ Yes ☐ No

If yes, specify the total amount (in Kilograms)

PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

Item 10 Distribution And Redistribution Of Licensed Materials

Item 10.1 Radiopharmaceuticals (Check both boxes)

☐ We will confirm that radiopharmaceuticals will be prepared under the supervision of an ANP or will be obtained from a supplier authorized pursuant to **12VAC5-481-480 I**, or under equivalent NRC or other Agreement State requirements;

AND

☐ We will describe all licensed material to be distributed or redistributed.

Item 10.2 Generators (Check all boxes if using generators)

☐ Confirm that the generators will be obtained from a manufacturer licensed pursuant to **12VAC5-481-480 I**, or under equivalent NRC or other Agreement State requirements.

AND

☐ Confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging.

Item 10.3 Redistribution Of Generators (Check all boxes if redistributing generators)

☐ We will submit a description of the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of migration of radioactive fluids out of the generator during transport.

AND

☐ Confirm that the manufacturer's packaging and labeling will not be altered.

AND

☐ Confirm that the generator will not be distributed beyond the expiration date shown on the generator label.

AND

☐ Confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator.

AND

☐ Confirm that only generators used in accordance with the manufacturer's instructions will be redistributed.

Note: Although redistribution of used generators may be authorized by VDH, VDH approval does not relieve the licensee from complying with applicable FDA or other Federal or state requirements.

Item 10.4 Redistribution Of Sealed Sources – For Brachytherapy Or Diagnosis (Check all boxes if redistributing sealed sources, for brachytherapy or diagnosis)

☐ Confirm that the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued in pursuant to **12VAC5-481-480 J**, or under equivalent NRC or other Agreement State requirements.

AND

☐ Confirm that the manufacturer's packaging, labeling and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

Item 10.5 Redistribution Of Calibration And Reference Sealed Sources (Check all boxes if redistributing calibration and reference sealed sources)

☐ Confirm that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a person licensed pursuant to **12VAC5-481-480 J**, or under equivalent NRC or other Agreement State requirements, to initially distribute such sources.

AND

☐ Confirm that the manufacturer's labeling and packaging will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

Item 10.6 Redistribution Of Prepackaged Units For In-Vitro Tests (Check box if redistributing prepackaged units for In-vitro tests)

☐ Confirm that the prepackaged units for in-vitro tests to be redistributed will have been obtained from a manufacturer licensed to distribute the prepackaged units for in-vitro tests pursuant to **12VAC5-481-480 G**, or under equivalent NRC or other Agreement State requirements.

Item 10.7 Redistribution To General Licensee (Check all boxes if redistributing to a general licensee)

☐ Confirm that the manufacturer's packaging and labeling of the prepackaged units for in-vitro tests will not be altered in any way.

AND

☐ Confirm that each redistributed prepackaged unit for in-vitro tests will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees.

Item 10.8 Redistribution To Specific License (Check box)

☐ Confirm that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed prepackaged units for in-vitro test will NOT reference general licenses, exempt quantities, or VDH, NRC, or Agreement State regulations that authorize a general license.

PREPARATION OF RADIOPHARMACEUTICALS

Item 11 Preparation Of Radiopharmaceuticals (Check box)

☐ We will attach a document that indicates the types of radiopharmaceuticals preparation activities we intend to perform (e.g.; compounding of Iodine-131 capsules, radioiodination, and technetium-99m kit preparation). (Document is attached)

SERVICE ACTIVITIES

Item 12 Service Activities (Check box)

☐ We will submit specific procedures for all radiation protection services that we intend to provide to other licensees (e.g. customers). (Procedures are attached)

FACILITIES AND EQUIPMENT

Item 13 Facilities And Equipment (Check boxes and attach diagram.)

☐ We will provide copies of a license from the State Board of Pharmacy; or evidence that we are operating as a nuclear pharmacy within a state medical institution.

Note: There may be a jurisdiction that does not recognize the practice of commercial radiopharmacy. In these cases, the applicant must submit evidence that it is registered or licensed with the FDA as a drug manufacturer.

AND

☐ We will provide a description of the facilities and equipment to be made available where radioactive material will be used. A diagram should provide be submitted showing the entire facility and identify activities conducted in all contiguous areas surrounding the facility. Diagrams should be drawn to specified scale, or dimensions should be indicated. For additional information refer to VAREG 'Guidance for Commercial Radiopharmacy'. (Description is attached)

RADIATION SAFETY PROGRAM

Item 14 Radiation Safety Program

Item 14.1 Audit Program

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

Item 14.2 Radiation Monitoring Instruments (Check one box)

☐ We will use equipment that meets the radiation monitoring instrument specifications and implement the survey meter calibration program published in Appendix J of VAREG 'Guidance for Commercial Radiopharmacy'.

OR

☐ We will use equipment that meets the radiation monitoring instrument specifications published in Appendix J of VAREG 'Guidance for Commercial Radiopharmacy', and instruments will be calibrated by licensees authorized by VDH, the NRC or another Agreement State.

OR

☐ We will provide a description of alternative equipment to be used for radiation monitoring and alternative procedures for the calibration of radiation monitoring equipment. (Procedures are Attached)

Item 14.3 Material Receipt And Accountability (Check all boxes)

☐ We have developed, and will implement and maintain, written procedures for safely opening packages that meet the requirements in **12VAC5-481-900**.

AND

☐ We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed 6 months.

AND

☐ We have developed, and will implement and maintain written procedures for radioactive material accountability and control to ensure that:

1. License possession limits are not exceeded;
2. Radioactive material in storage is secured from unauthorized access or removal;
3. Radioactive material not in storage is maintained under constant surveillance and control; and
4. Records of receipt, transfer, and disposal of licensed material are maintained.

(Procedures are attached)

Item 14.4 Occupational Dosimetry (Check all that apply)

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

AND / OR

☐ We will maintain for inspection by the agency, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in **12VAC5-481-640**.

Item 14.5 Public Dose

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

Item 14.6 Safe Use Of Radionuclidies And Emergency Procedures (Check box)

☐ We will develop, implement and maintain safe use of radionuclides and emergency procedures that meets the criteria in the section titled 'Safe Use of Radionuclides and Emergency Procedures' in VAREG 'Guidance for Commercial Radiopharmacy'. (Procedures are Attached)

Item 14.7 Surveys (Check one box)

☐ We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix R of VAREG 'Guidance for Commercial Radiopharmacy'.

OR

☐ We will develop, implement and maintain written procedures for a survey program that specifies the performance of radiation and contamination level surveys in restricted and unrestricted areas, personnel contamination monitoring, action levels, and the frequencies and records maintenance of those surveys and monitoring that meet the requirements in **12VAC5-481-100, 12VAC5-481-750 and 12VAC5-481-1000**. (Procedures attached)

Item 14.8 Dose Calibrator And Other Dosage Measuring Equipment (Check all that apply)

☐ We will describe the types of systems (measurement or combination of measurement and calculation) that we intend to use for the measurement of alpha-beta, and photon-emitting radioactive drugs.

AND

☐ We will develop, implement and maintain a written procedure for the performance of dose measurement system checks and tests that meet the requirements in **12VAC5-481-480 I**. (Procedures are attached)

AND EITHER

☐ We will provide, if applicable, a sample calculation for determining beta-correction factors for dose calibrators with ionization chambers.

OR

☐ We will include, if applicable, a means for ensuring the accuracy of beta-correction factors supplied by the instrument manufacturer, or other entity.

Item 14.9 Radioactive Drug Labeling For Distribution (Check both boxes)

☐ We will describe all labels, indicating the colors to be used, that will accompany the products and describe where each label is placed (e.g. on the "transport radiation shield" or the container used to hold the radioactive drug); (Description is attached)

AND

☐ Agree to affix the required labels to all "transport radiation shields" and each container used to hold the radioactive drugs.

Item 14.10 Radioactive Drug Shielding For Distribution (Check box)

☐ For each drug to be distributed, we will (except for products intended for redistribution without manipulation and in the manufacturer's original shipping package):

- Indicate the radionuclide and the maximum activity for each type of container (e.g. vial, syringe);
- Describe the type and thickness of the "transport radiation shield" provided for each type of container; and
- Indicate the maximum radiation level to be expected at the surface of each "transport radiation shield" when the radioactive drug container is filled with the maximum activity.

NOTE: It is not acceptable to State that the applicant will comply with DOT regulations. The dose rate limits that DOT imposes apply to the surface of the package, not the surface of the "Transport Radiation Shield."

Item 14.11 Leak Test (Check one box)

☐ Leak tests will be performed by an organization authorized by VDH, the NRC or another Agreement State to provide leak testing services to other licensees; or by using a leak test kit supplied by an organization licensed by VDH, the NRC or another Agreement State to provide leak test kits to other licensees according to kit supplier's instructions.

License number of organization authorized to perform or analyze leak test (Specify whether VDH, NRC, or another Agreement State):

Organization Name: _____ License Number: _____
Issuing Agency: _____

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

OR

☐ We will perform our own leak testing and sample analysis. We will follow the procedures in Appendix L of VAREG 'Guidance for Commercial Radiopharmacy'.

OR

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

WASTE DISPOSAL AND TRANSFER

Item 15 Waste Disposal And Transfer

Item 15.1 Waste Management (Check box)

☐ We will develop, implement and maintain procedures for waste collection, storage and disposal by any of the authorized methods described in the section titled 'Waste Management' of VAREG 'Guidance for Commercial Radiopharmacy'. We will contact VDH for guidance to obtain approval of any method(s) of waste disposal other than those discussed in the section titled 'Waste Management' of VAREG 'Guidance for Commercial Radiopharmacy'. (Procedures are attached)

Item 15.2 Returned Waste From Customers (Check one box)

☐ We will follow the procedures for returned waste from customers in Appendix S of VAREG 'Guidance for Commercial Radiopharmacy'.

OR

☐ We will develop, implement and maintain procedures for returned waste from customers, that will meet the criteria in the section titled 'Returned Waste from Customers' in VAREG 'Guidance for Commercial Radiopharmacy'. (Procedures are attached)

SPECIFIC LICENSE FEE

Item 16 License Fees (Refer to **12VAC5-490**)

License fee enclosed

☐ Yes Amount Enclosed $_____

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

Item 17

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

SIGNATURE - Applicant Or Authorized Individual	Date signed

Print Name and Title of above signatory

Revision 1 August 1, 2012

Attachment A
Radiopharmacy Applicant's Checklist

Yes	No	Item	Material Needed
		Application	Used the correct form (New for new licensees or Renewal for renewing licensees)
		Application	Checked at least one box and filled in all the required information, as needed, for all Items
		Item 5	Attached organization chart and training information of the Radiation Safety Officer
		Item 6	Attached pharmacist certificates and training information for the Authorized Nuclear Pharmacist(s)
		Item 7	Attached names and identified types, quantities, and proposed use of licensed material with training information for Authorized User(s)
		Item 8.1	Attached training course information
		Item 8.2	Attached training course information, if needed
		Item 10.3	Attached description of procedures for safely repacking
		Item 11	Attached preparation of radiopharmaceuticals procedure(s)
		Item 12	Attached service activities procedure
		Item 13	Attached license from Board of Pharmacy and facility diagram
		Item14.2	Checked box or attached alternate procedure
		Item 14.3	Attached procedures for receipt and security of licensed material
		Item 14.6	Attached safe use of radionuclides procedure
		Item 14.7	Checked box or attached alternate procedure
		Item 14.8	Checked box and attached dose measurement procedure
		Item 14.9	Attached description of drug labeling
		Item 14.11	Checked box(es) or attached alternate procedure
		Item 15.1	Attached waste management procedure
		Item 15.2	Checked box or attached alternate procedure

Appendix B:

VDH Form,
‘Certificate of Disposition of Materials’

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

CERTIFICATE OF DISPOSITION OF MATERIALS

Completion of this form is required to complete termination of a Radioactive Material License as outlined in **12VAC5-481-510**. Failure to provide information will result in this request for termination of a specific license not being processed.

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

CONTACT INFORMATION

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

TERMINATION AND DISPOSITION INFORMATION

The following information is provided in accordance with **12VAC 5-481-510.** (Check all that apply)

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

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

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

☐ Transferred to: Name Address

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

Issued by (Licensing Agency):

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

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

☐ Other (Attach additional pages)

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

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

Name:

Address:

Contact Person Telephone Number: ( ) - x

Additional remarks (Attach additional pages if necessary.)

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

Item 10.

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

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

Print Name and Title of above signatory

Appendix C:

Sample Delegation Letter

SAMPLE CORRESPONDENCE DELEGATION LETTER

[date]

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

To Director, Radioactive Materials Program:

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

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

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

_____ _____ _____

Signature Title Date

Appendix D:

Reserved

Appendix E:

Reserved

Appendix F:

Information Needed for Transfer of Control Application

Information Needed for Transfer of Control Application

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

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

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

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

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

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

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

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

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

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

Appendix G:

Model Formats for Documenting Training and Experience for Individuals Responsible for Radiation Protection Program

Authorized User or Radiation Safety Officer Training
In Basic Radioisotope Handling Techniques

Name (Last, First, Initial)

Location of Training	Dates	Title	Total Hours	Breakdown of Course in Clock Hours				
				RPP	BH	IR	INST	REG
			Totals					

RPP **Radiation Protection Principles**

BH **Biological Hazards**

IR **Ionizing Radiation Units & Characteristics**

INST **Radiation Detection Instrumentation**

REG **VDH Rule**

Authorized User and Radiation Safety Officer Experience Handling Radioisotopes

(Actual use of radioisotopes under the supervision of an Authorized User or Radiation Safety Officer, respectively)

Name (Last, First, Initial)

Isotope(s) Used	Maximum amount Used at any one time	Location of Use	Purpose of Use*	Total Hours of Experience

*** Purpose of Use:**

- **Shipping, receiving, and performing related radiation surveys**
- **Using and performing checks for proper operation of dose calibrators, survey meters, and other instruments used to measure photon- and high energy beta-emitting radionuclides**
- **Using and performing checks for proper operation of instruments used to measure alpha- and low energy beta- emitting radionuclides**
- **Calculating, assaying, and safely preparing radioactive materials**
- **Use of procedures to prevent or minimize contamination and/or use of proper decontamination procedures**

Authorized Nuclear Pharmacist
Training in Basic Radioisotope Handling Techniques

Name (Last, First, Initial)

Location of Training	Dates	Title	Total Hours	Breakdown of Course in Clock Hours				
				RPP	BH	IR	INST	REG
			Totals					

Signature of Preceptor Authorized Nuclear Pharmacist: **"I certify that the above described training/experience has been satisfactory completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy."**	**Signature:**	**Date:**

RPP	**Radiation Protection Principles**	**BH**	**Biological Hazards**
IR	**Ionizing Radiation Units & Characteristics**	**INST**	**Radiation Detection Instrumentation**
REG	**VDH Rule**		

Authorized Nuclear Pharmacist
Experience Handling Radioisotopes

(Actual use of radioisotopes under the supervision of an Authorized User or Radiation Safety Officer, respectively)

Name (Last, First, Initial)

Isotope(s) Used	Maximum amount Used at any one time	Location of Use	Purpose of Use*	Total Hours of Experience

Signature of Preceptor Authorized Nuclear Pharmacist: **"I certify that the above training/experience has been satisfactory completed and that the individual has achieved a level of competency sufficient to independently operate a Nuclear Pharmacy."**	**Signature:**	**Date:**

*** Purpose of Use**

- **Shipping, receiving, and performing related radiation surveys**
- **Using and performing checks for proper operation of dose calibrators, survey meters, and other instruments used to measure photon- and high energy beta-emitting radionuclides**
- **Using and performing checks for proper operation of instruments used to measure alpha- and low energy beta-emitting radionuclides**
- **Calculating, assaying, and safely preparing radioactive materials**
- **Use of procedures to prevent or minimize contamination and/or use of proper decontamination procedures**

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

TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION STATEMENT – G
(Authorized Nuclear Pharmacist)

The Virginia Department of Health is requesting disclosure of all information on this statement for the purpose of authorizing an individual to work with radioactive material. Failure to provide any information may result in denial or delay of authorizing an individual to work with radioactive material.

Instructions: Complete all applicable items. Refer to VAREG 'Guidance for Medical Use of Radioactive Material'. Use supplementary sheets where necessary. Retain one copy and submit original of the document to the Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219.

PART I TRAINING AND EXPERIENCE

Describe training and experience in sufficient detail to match the training and experience criteria in applicable regulations.

1. Name of Individual

2. State Licensure

☐ A copy of license to practice pharmacy in Virginia is attached.

3. Certification (attach copy of current certificate)

Specify Board	Category	Month and Year Certified

Note: Items 4-6 do not need to be completed when using Board Certification to meet **12VAC5-481 Part VII**, training and experience requirements.

4. Classroom and Laboratory Training

Description of Training	Training Location	*Clock Hours*	*Dates of Training*
Radiation Physics and Instrumentation			
Radiation Protection			
Mathematics Pertaining to Use and Measurement of Radioactivity			
Radiation Biology			

5. Supervised Work Experiences

Description of Experience	Dates of Experience
Shipping, receiving and performing radiation related surveys	
Using and performing checks for proper operation of survey meters and instruments used to determine the activity of dosages.	
Calculating, assaying and safely preparing dosages.	
Using administrative controls to avoid medical events in the administration of radioactive material.	
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures.	

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

6. Preceptor Approval and Attestation

☐ I am an authorized nuclear pharmacist.

I attest that the individual named in **Item 1**:

☐ Has satisfactorily completed the training requirements in **12VAC5-481-1770**;

AND

☐ Has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Name of License on which Preceptor is Authorized	Materials License Number –(Indicate which Agreement State or if NRC)
Print Name of Preceptor	
SIGNATURE - Preceptor	Date Signed

Appendix H:

Duties and Responsibilities of the Radiation Safety Officer

Duties and Responsibilities of the Radiation Safety Officer

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

- General surveillance is provided over all activities involving radioactive material; including routine monitoring, special surveys, and responding to events;
- Incidents are responded to, investigated and cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Proper authorities are notified of incidents such as damage, fire, or theft;
- Corrective actions are developed, implemented, and documented when violations of the rule or license conditions or program weaknesses are identified;
- Immediate termination of all activities following any unsafe condition or activity that is found to be a threat to public health and safety;
- Acts as the primary source of radiation protection information for personnel at all levels of responsibility;
- All radiation workers are properly trained;
- Procedures for the safe use of radioactive materials are developed and implemented;
- The licensee's procedures and controls, based upon sound radiation protection principles, are periodically reviewed to ensure that occupational doses and doses to members of the public are as low as is reasonably achievable (ALARA). Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit;
- Prospective evaluations are performed of occupational exposures and those individuals likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits are provided personnel monitoring devices;
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- The performance of fume hoods and gloveboxes used for volatile radioactive work are monitored for proper operation;
- The receipt, opening, and delivery of all packages of radioactive material arriving at the nuclear pharmacy are overseen and coordinated;
- An inventory of all radioactive materials is maintained and the types and quantities of radionuclides at the facility are limited to the forms and amounts authorized by the license;
- Sealed sources are leak-tested at required intervals;
- There is effective management of the radioactive waste program, including effluent monitoring;
- Packaging and transport of radioactive material is in accordance with all applicable VDH and DOT requirements;
- An up-to-date license is maintained and amendment and renewal requests and notifications of new ANP's are submitted in a timely manner;
- Radiation safety program audits are performed at least annually and documented;
- Acts as liaison to VDH; and
- All required records are properly maintained

Appendix I:

Suggested Commercial Radiopharmacy Audit Checklist

Suggested Commercial Radiopharmacy Audit Checklist

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

Date of this Audit:_____ Date of last Audit:_____

Next Audit Date:_____

Auditor_____ Date_____
(Signature)

Management Review_____ Date_____
(Signature)

Audit History

A. Last audit of this location conducted on (date)_____

B. Were previous audits conducted at intervals not to exceed 12 months? (**12VAC5-481-630**)

C. Were records of previous audits maintained? (**12VAC5-481-990**)

D. Were any deficiencies identified during last two audits or two years, whichever is longer?

E. Were corrective actions taken? (Look for repeated deficiencies.)

Organization and Scope of Program

A. If the mailing address or places of use changed, was the license amended? (**12VAC5-481-500**)

B. If ownership changed or bankruptcy filed, was VDH's prior consent obtained or was VDH notified? (**12VAC5-481-500**)

C. Authorized Nuclear Pharmacists

1. New ANP since last audit? If so, does new ANP meet's VDH requirements? (**12VAC5-481-10; 12VAC5-481-480**)
2. If an individual began work as an ANP, was VDH notified within 30 days or was the license amended? (**12VAC5-481-480**)

D. Radiation Safety Officer

1. New RSO since last audit? If so, does new RSO meet VDH's training requirement?
2. If the RSO was changed, was license amended?
3. Is RSO fulfilling his/her duties?
4. To whom does RSO report to?

E. Authorized Users

1. New AU since last audit? If so, does new AU meet VDH's requirements?
2. If an AU was added, was the license amended?

F. If the designated contact person for VDH changed, was VDH notified?

G. Type and quantity of radioactive material

1. Does the license authorize all of the regulated radionuclides possessed?
2. Is actual possession of those radionuclides within the limits on the license?

Facilities

A. Are facilities as described in VDH's license application?

B. If facilities have changed, has the license been amended?

Equipment and Instrumentation

A. Sufficient numbers of portable and fixed radiation monitors (i.e., points of entry and exit into hotlab, package shipping area)?

B. Do survey meters meet VDH's criteria? (**12VAC5-481-750**)

C. Are calibration records maintained? (**12VAC5-481-1000**)

D. Are there sufficient lead shields (L-block, etc.) for work with radionuclides?

E. Are generators housed in separate room and/or properly shielded to keep doses ALARA?

F. Are procedures established for identifying, evaluating and reporting safety component defects?

G. Dose calibrators for Photon-emitters (**12VAC5-481-480**):

1. Constancy, at least once a day prior to assay of patient dosages (+/- 10%)?
2. Linearity, at installation and at required frequency (+/- 10%)?
3. Geometry dependence, at installation (+/- 10%)?
4. Accuracy, at installation and at required frequency (+/- 10%)?
5. After repair, adjustment, or relocation of the dose calibrator, were appropriate tests listed above repeated?

H. Dose Measurement Systems for Beta- and Alpha-emitters (**12VAC5-481-480**):

1. Calibrated for each isotope used, with that isotope?
2. Constancy, at least once each day, prior to assay of patient dosages (+/- 10%)?
3. Geometry dependence, at installation (+/- 10%)?
4. Accuracy, at installation and annually (+/- 10%)?
5. Linearity, at installation and quarterly (+/- 10%)?
6. After repair, adjustment, or relocation of the dose calibrator, were appropriate test above repeated?

Area Surveys and Contamination Control

A. Are area surveys being performed at applicable locations (i.e., hotlab and radioactive material storage locations) and required frequencies? Records maintained? (**12VAC5-481-1000**)

B. Are removable contamination surveys being performed at applicable locations and required frequencies? Records maintained? (**12VAC5-481-1000**)

C. Are appropriate corrective actions taken and documented when excess radiation or contamination levels are detected?

Leak Tests

A. Was each sealed source leak tested every six months or at other prescribed intervals?

B. Was the leak test performed according to the license?

C. Are records of results retained with the appropriate information included?

D. Were any sources found leaking if yes, was VDH notified?

Sealed Source Inventory

A. Is a record kept showing the receipt of each sealed source? (**12VAC5-481-100; 12VAC5-481-571**)

B. Are all sealed sources physically inventoried every six months?

C. Are records of inventory results with appropriate information maintained?

Training and Instructions to Workers

A. Were all workers who are likely to exceed 1mSv (100 mrem) in a year instructed annually per **12VAC5-481-2270**? Records maintained?

B. Were other workers trained as needed (e.g., radiopharmacy technicians, authorized users, couriers/drivers, ancillary personnel)? (**12VAC5-481-450**) Records maintained?

C. Are workers knowledgeable of applicable **12VAC5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation',** radiation protection procedures, emergency response procedures and license conditions?

D. HAZMAT training provided, if required? (**49 CFR 172.700-704**)

Material Use Control and Transfer

A. Are restricted and unrestricted areas delineated?

B. Are radioactive materials that are stored in a controlled or unrestricted area secured from unauthorized access or removal? (**12VAC5-481-840**)

C. Are radioactive materials that are in a controlled or unrestricted area and not in storage controlled and maintained under constant surveillance? (**12VAC5-481-840**)

D. Procedures for receiving and opening packages? (**12VAC5-481-900**)

E. Transfer of radioactive material only to authorized recipients? (**12VAC5-481-570**) Records of receipt and transfer? (**12VAC5-481-100**; **12VAC5-481-571**)

Personnel Radiation Protection

A. Are ALARA considerations incorporated into the radiation protection program? (**12VAC5-481-630**)

B. Were prospective evaluations performed showing that unmonitored individuals receive less than 10% of the limit? (**12VAC5-481-750**; **12VAC5-481-760**)

C. Did unmonitored individuals' activities change during the year which could put them over 10% of the limit?

D. If yes to C. above, was a new evaluation performed?

E. Is external dosimetry required (individuals likely to receive >10% of the limit)? And is dosimetry provided to these individuals?

1. Is the dosimetry supplier NVLAP approved? (**12VAC5-481-750**)
2. Are the dosimeters exchanged at appropriate frequency?
3. Are dosimetry reports reviewed by the RSO when they are received?
4. Are the records on VDH forms or equivalent? (**12VAC5-481-1020; 12VAC5-481-1040**) VDH form, 'Occupational Exposure Record for a Monitoring Period' completed?
5. Declared pregnant worker/embryo/fetus
   a. If a worker declared her pregnancy, did the licensee ensure that the dose to the embryo or fetus during the entire pregnancy was less than 5 mSv (500 mR)? (**12VAC5-481-710**) Were records kept of embryo/fetus dose per **12VAC5-481-1040**?

F. Monitoring for internal dose if individuals likely to receive >10% of ALI?

G. Are workers notified anually of their exposures?

H. Are records of exposures, surveys, monitoring, and evaluations maintained per **12VAC5-481-1000** and **12VAC5-481-1040*?***

Waste Management

A. Waste storage areas

1. Is storage area properly posted? (**12VAC5-481-860**)
2. Are containers properly labeled? (**12VAC5-481-880**)

B. Decay-in-Storage

1. Do radionuclides being stored all have half-lives less then 120 days (or 300 days if permitted by license condition)?
2. Are radionuclides being segregated for storage according to half-life?
3. Each radionuclide in radioactive waste stored for a minimum of 10 half-lives?

4. Before waste is disposed of:
   a. Survey performed at the container surface with an appropriate survey instrument set on its most sensitive scale with no interposed shielding to determine that its radioactivity cannot be distinguished from background?
   b. All radiation labels removed or obliterated, as appropriate?
5. Record Keeping?

C. Disposal by release into sanitary sewerage.

1. Is radioactive material readily soluble (or readily dispersible biologically material) in water? (**12VAC5-481-910; 12VAC5-481-930**)
2. Quantity of radioactive material that the licensee releases into the sewer each month averaged over the monthly volume of water released into the sewer does not exceed the concentration specified in **12VAC5-481-3690**?
3. If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit in **12VAC5-481-3690** does not exceed unity?
4. Total quantity of radioactive material released into the sanitary sewerage system in a year does not exceed the limits specified in **12VAC5-481-930**?

D. Transfer to Authorized Recipient

1. Is waste transferred to a person specifically authorized to receive it? (**12VAC5-481-570; 12VAC5-481-910)** Is waste properly manifested? (**12VAC5-481-1060)**

Receipt of Radioactive Waste from Customers

A. Waste returned consists only of items that contained radioactive materials that the radiopharmacy supplied (e.g., pharmacy supplied syringes, vials)?

B. Waste package checked for removable contamination upon receipt?

Effluents

A. Effluents from materials being maintained as low as reasonably achievable (ALARA)?

B. Fume hoods checked to confirm an adequate airflow?

C. Effluent monitored to determine activity being released?

D. Filters being maintained according to the manufacturer's instructions and pharmacy procedures?

Public Dose

A. Public access to radioactive materials and exposure to effluents controlled in a manner to keep doses below 1 mSv (100 mrem) in a year? (**12VAC5-481-720**)

B. Air emissions maintained below constraint limit of 0.1 mSv (10 mrem) in a year? (**12VAC5-481-630**)

C. Survey or prospective evaluation performed per **12VAC5-481-730**? Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?

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

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

Use and Emergency Procedures

A. Procedures for safe use of radioactive materials and emergency procedures developed and implemented?

B. Do the procedures contain the required elements?

C. Radioactive materials being handled safely?

D. Staff wearing protective clothing and personnel monitors as appropriate?

E. Assistance coordinated with outside agencies for emergency response (e.g., fire department, VDH)?

F. Did any emergencies occur?

1. If so, were they handled properly?
2. Were appropriate corrective actions taken?
3. Was VDH notification or reporting required? (**12VAC5-481-1090; 12VAC5-481-1100; 12VAC5-481-1110**)

Transportation

A. DOT-7A or other authorized packages used? (**49 CFR 173.415** and **49 CFR 173.416(b)**)

B. Package performance test records on file?

C. Package has two labels (ex. Yellow-II) with TI, Nuclide, Activity, and Hazard Class? (**49 CFR 172.403; 49 CFR 173.441**)

D. Package properly marked? (**49 CFR 172.301; 49 CFR 172.304; 49 CFR 172.310; 49 CFR 172.324**)

E. Package closed and sealed during transport? (**49 CFR 173.475(f)**)

F. Shipping papers prepared and used? (**49 CFR 172.200(a)**)

G. Shipping papers contain proper entries? (Shipping name, Hazard Class, Identification Number {UN Number}, Total Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity {SI units required}, category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, Emergency Response Information, and Cargo Aircraft Only {If applicable}) (**49 CFR 172.204; 49 CFR 172.604**)

H. Shipping papers within drivers reach and readily accessible during transport? **(49 CFR 177.817(e)**)

I. Package secured against movement? (**49 CFR 177.834**)

J. Any incidents reported to DOT? (**49 CFR 171.15; 49 CFR 171.16**)

Auditor's Independent Survey Measurements (if made)

A. Describe the type, location, and results of measurements. Does any radiation level exceed regulatory limits? (**12VAC5-481-630; 12VAC5-481-720**)

Notification and Reports

A. Was any radioactive material lost or stolen? Were reports made? (**12VAC5-481-1090**)

B. Did any reportable incidents occur? Were reports made? (**12VAC5-481-1100; 12VAC5-481-1110**)

C. Did any overexposures and high radiation levels occur? Reported? (**12VAC5-481-1100; 12VAC5-481-1110**)

D. Were any contaminated packages or packages with surface radiation levels exceeding 200 mrem received? Reported to VDH?

E. If any events (as described in items A. through D. above) did occur, what was the root cause? Were appropriate notifications made and corrective actions taken?

F. Is the management/RSO aware of the emergency phone number for VDH (804-864-8150 during business hours, (800) 468-8892 after hours)?

Posting and Labeling

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

B. **12VAC5-481 'Virginia Radiation Protection Regulations', Part IV and X,** license documents and operating procedures posted or a summary of where to find the documents is posted? (**12VAC5-481-2260**)

C. Emergency procedures are posted in a conspicuous location?

D. Other postings and labeling? (**12VAC5-481-850; 12VAC5-481-860; 12VAC5-481-880**)

Record Keeping for Decommissioning

A. Records kept of information important to decommissioning? (**12VAC5-481-450 C**)

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

Information Notices

A. Are VDH Information Notices received?

B. Appropriate training and action taken in response?

Special License Conditions or Issues

A. Did auditor review special license conditions or other issues?

Deficiencies Identified in Audit; Corrective Actions

A. Summarize problems/deficiencies identified during audit.

B. If problems/deficiencies identified in this audit, describe corrective actions planned or taken by the facility. Include date(s) when corrective actions are implemented.

C. Provide any other recommendations for improvement.

Evaluation of Other Factors

A. Senior licensee management is appropriately involved with the radiation protection program and/or RSO oversight?

B. RSO has sufficient time to perform his/her radiation safety duties?

C. Licensee has sufficient staff to support the radiation protection program?

Appendix J:

Radiation Monitoring Instrument Specifications and Survey Instrument Calibration Program

The specifications in **Table 6** will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facility.

Table 6. Typical Survey Instruments (Instruments used to measure radiological conditions at licensed facility.)

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

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

Instrument Calibration Program

Training

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

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

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

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

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

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

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

Procedure for Calibrating Survey Instruments

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

- Approximate a point source;
- Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified to be within ± 5% accuracy by National Institutes of Standards and Technology (NIST);
- Approximate the same energy and type of radiation as the environment in which the calibrated device will be employed; and
- For dose rate and exposure rate instruments, the source should be strong enough to give an exposure rate of at least about 7.7×10^{-6} coulombs/kilogram/hour (30 mR/hr) at 100 cm [e.g., 3.1 gigabecquerels (85 mCi) of cesium-137 or 7.8×10^{2} megabecquerels (21 mCi) of cobalt-60].

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

- Linear readout instruments with a single calibration control for all scales shall be adjusted at the point recommended by the manufacturer or at a point within the normal range of use. Instruments with calibration controls for each scale shall be adjusted on each scale. After adjustment, the response of the instrument shall be checked at approximately 20% and 80% of full scale. The instrument's readings shall be within ± 15% of the conventionally true values for the lower point and ± 10% for the upper point;
- Logarithmic readout instruments, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. The instrument shall be adjusted for

each scale according to site specifications or the manufacturer's specifications. After adjustment, calibration shall be checked at a minimum of one point on each decade. Instrument readings shall have a maximum deviation from the conventionally true value of no more than 10% of the full decade value;

- Meters with a digital display device shall be calibrated the same as meters with a linear scale;
- Readings above 2.58 X 10^{-4} coulomb/kilogram/hour (1 R/hr) need not be calibrated, but such scales should be checked for operation and response to radiation; and
- The inverse square and radioactive decay law should be used to correct changes in exposure rate due to changes in distance or source decay.

Surface Contamination Measurement Instruments

Survey meters' efficiency must be determined by using radiation sources with similar energies and types of radiation that the survey instrument will be used to measure.

If each scale has a calibration potentiometer, the reading shall be adjusted to read the conventionally true value at approximately 80% of full scale, and the reading at approximately 20% of full scale shall be observed. If only one calibration potentiometer is available, the reading shall be adjusted at mid-scale on one of the scales, and readings on the other scales shall be observed. Readings shall be within 20% of the conventionally true value.

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

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

- Approximate the geometry of the samples to be analyzed;
- Have its apparent source activity traceable by documented measurements to a standard certified to be within ± 5% accuracy by National Institutes of Standards and Technology (NIST); and
- Approximate the same energy and type of radiation as the samples that the calibrated device will be used to measure.

Calibration

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

Calibration Records

Calibration reports, for all survey instruments, will indicate the procedure used and the data obtained. The description of the calibration will include:

- The owner or user of the instrument;
- A description of the instrument, including the manufacturer's name, model number, serial number, and type of detector;
- A description of the calibration source, including the exposure rate at a specified distance or activity on a specified date;
- For each calibration point, the calculated exposure rate or count rate, the indicated exposure rate or count rate, the deduced correction factor (the calculated exposure rate or count rate divided by the indicated exposure rate or count rate), and the scale selected on the instrument;
- For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular);

- For instruments with internal detectors, the angle between radiation flux field and a specified surface of the instrument;
- For detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure;
- The exposure rate or count rate from a check source, if used; and
- The name of the person who performed the calibration and the date it was performed.

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

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

Air Sampler Calibration

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

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

Frequency of Calibration

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

Error Limit for Measurement of Air Sample Volume

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

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

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

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

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

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

E_V: The most probable value of the cumulative percentage error in the determination of the total air volume sampled can be calculated from the following equation, provided there are no additional significant sources of errors:

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

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

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

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

Note: The calibration factor should be based on two kinds of determinations. First, correction factors should be determined at several flow rates distributed over the full-scale range. Each flow rate correction factor should be determined while adjusting flow rates upscale and again while adjusting flow rates downscale, and the two sets of data should be compared. Second, subsequent calibrations should compare the new correction factor to those determined during the previous calibration. If observed differences are significant compared to the overall volume error limit of 20%, an additional error term should be included in the calculation above.

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

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

Where: Vs = volume at standard conditions (760 mm & 0 degree C)
V1 = volume measured at conditions P1 and T1
T1 = temperature of V1 in K
P1 = pressure of V1 in mm Hg

Documentation of Calibration of Air Metering Devices

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

References: NRC Regulatory Guide 8.25, Revision 1, 'Air Sampling in the Workplace'; and NUREG – 1400, 'Air Sampling in the Workplace', can be accessed at the NRC website www.nrc.gov.

Additional References:

1. The Health Physics & Radiological Health Handbook, Revised Edition, Edited by Bernard Shleien.
2. ANSI N323A- 1997, 'Radiation Protection Instrumentation Test and Calibration'. Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018 or ordered electronically at the following address: www.ansi.org;
3. 'Air Sampling Instruments', American Conference of Governmental Industrial Hygienists, 7th Edition, dated 1989.

Appendix K:

Public Dose

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

Licensees must ensure that:

- The radiation doses received by individual members of the public do not exceed 1 millisievert (mSv) [100 millirem (mrem)] in one calendar year resulting from the licensee's possession and/or use of licensed materials. (**12VAC5-481-720**);
- Air emissions of radioactive material to the environment will not result in exposures to individual members of the public in excess of 0.1 mSv (10 mrem) (TEDE) in one year from those emissions. (**12VAC5-481-630**); and
- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour. (**12VAC5-481-720**)

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

Doses to Members of the Public
INCLUDES doses from:

- Radiation and/or radioactive material released by a licensee
- Sources of radiation under the control of a licensee
- Air effluents from sources of licensed radioactive materials
- Licensed material in transportation or storage at the licensee's facility

BUT, DOES NOT INCLUDE doses from:

- Sanitary sewerage discharges from licensees
- Natural background radiation
- Medical administration of radioactive material
- Voluntary participation in medical research

Note: Typical unrestricted areas may include offices, shops, areas outside buildings, property, and storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials. However, the licensee may control access to these areas for other reasons such as security.

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

- Demonstrating by measurement or calculation that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv (100 mrem) from all exposure pathways, and does not exceed 0.1 mSv (10 mrem) from air emissions.;
- Demonstrating that the annual average concentration of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area does not exceed the values specified in **12VAC5-481-3690, Table 2** (20% of the values for gaseous effluents); and
- If an individual were continuously present in an unrestricted area the dose from external sources would not exceed 0.02 mSv (2 mrem) in an hour and 0.5 mSv (0.05 rem) in a year.

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

Measurements

The licensee may use measurements to demonstrate that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv (100 mrem) and does not exceed 0.1 mSv (10 mrem) from air emissions. These measurements may include:

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

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

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

Calculation Method

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

The public dose limit applies to the individual who is likely to receive the highest dose from licensed operations; therefore, the dose calculations must consider the location with the potential for the highest internal and external exposures. This calculation should assume that the individual was continuously present 24 hours a day, 365 days a year, or an occupancy factor of 1 (see **Table 7**). If the result of the calculation using an occupancy factor of 1 demonstrates that the public dose and constraint limits are not exceeded, then there is no need for further evaluation.

If the calculation demonstrates that either the public dose or constraint limit is exceeded with an occupancy factor of 1, then more realistic assumptions of the individual's occupancy at the points of highest internal and external exposures must be made. The licensee may use the occupancy factors in **Table 7** or may calculate a specific occupancy factor by determining the likely fraction of time that the individual is present.

Table 7: Standard Occupancy Factors

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

Calculating the Annual Dose to an Individual Member of the Public:

- Identify all potential sources of external and internal exposure to the member of the public.
- Identify all locations of use, transport, or storage of radioactive material.
- Perform surveys of all locations of use, transport, or storage of radioactive material.
- Identify from survey data, at each location, maximum levels of dose rates.
- Calculate predicted occupancy factors at points of maximum dose rates.
- Multiply dose rates by number of hours in a year to produce the maximum annual dose.
- Multiply the maximum annual dose by the occupancy factors to get the annual dose.

Records

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

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

Appendix L:

Leak Test Program

Training

Before allowing an individual to perform leak testing, the licensee must ensure that he or she has sufficient classroom and on-the-job training to show competency in performing leak tests independently.

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

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

Appropriate on-the-job-training consists of:

- Observing authorized personnel collecting and analyzing leak test samples; and
- Collecting and analyzing leak test samples under the supervision and in the physical presence of an individual authorized to perform leak tests

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests will be analyzed in a low-background area.
- Use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed.
- Analyze the leak test sample using an instrument that is appropriate for the type of radiation to be measured (NaI(Tl) well counter system, liquid scintillation, gas flow proportional counter).
- If the sensitivity of the counting system is unknown, the minimum detectable activity (MDA) needs to be determined. The MDA may be determined using the following formula:

$$MDA = \frac{3 + 4.65(bkg/t)^{1/2}}{E}$$

Where: MDA = minimum detectable activity in disintegration's per minute (dpm)
bkg = background count rate in counts per minute (cpm)
t = background counting time in minutes
E = detector efficiency in counts per disintegration

For example:

Where: bkg = 200 cpm
E = 10%, or 0.1
t = 2 minutes

$$MDA = \frac{3 + 4.65(200\ cpm/2\ minutes)^{1/2}}{(0.1)}$$

$$= 495\ dpm$$

Frequency for Conducting Leak Tests of Sealed Sources

Leak tests will be conducted at the frequency specified in the respective SSD Registration Certificate.

Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as sealed source serial number, radionuclide, activity.
- If available, use a survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 185 Bq (0.005 microcuries) of the radionuclide.
- Using the selected instrument, count and record background count rate.
- Check the instrument's counting efficiency using a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within ± 5% of the stated value and traceable to primary radiation standard such as those maintained by the National Institutes of Standards and Technology (NIST).
- Calculate efficiency.

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

  Where: cpm = counts per minute
  std = standard
  bkg = background
  Bq = becquerel
- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in Bq (or mCi).

  For example: $\frac{[(\text{cpm from wipe sample}) - (\text{cpm from bkg})]}{\text{efficiency in cpm/Bq}}$ = Bq on wipe sample
- Sign and date the list of sources, data, and calculations. Retain records for 5 years (**12VAC5-481-1010**). If the wipe test activity is 185 Bq (0.005 microcurie) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly. Also notify VDH.

Appendix M:

Transportation: DOT Regulations Applicable to Radiopharmacy Shipments

The major areas in the DOT regulations most relevant to commercial radiopharmacies for the transportation of radioactive material are:

- Hazardous Materials Table, **49 CFR 172.101, App. A**, list of hazardous substances and reportable quantities (RQ), Table 2: Radionuclides.

  For the majority of packages shipped by radiopharmacies to their customers, the proper shipping name to use will be "*Radioactive Material, N.O.S.*" Other shipments, involving primarily small quantities of radioactive material, and especially return shipments by customers, will likely be excepted packages of limited quantity. The DOT requirements for those shipments can be found in **49 CFR 173.421** and **173.422**.

  Likewise, for the majority of packages shipped by radiopharmacies, it will not be necessary to identify the radioactive material as a Hazardous Substance in accordance with **Table 2 of 49 CFR 172.101**. For the majority of radionuclides contained in packages from radiopharmacies (i.e., Technetium-99m and Thallium-201) the threshold for identification as a Hazardous Substance is on the order of 100 to 1000 curies, which is significantly more than is contained in the typical shipment. However, for shipments containing more than 10 millicuries of Iodine-131, the packages and shipping papers must include the "*RQ*" designation of the shipment as containing a reportable quantity. The "*RQ*" must appear either before or after the basic description of the shipment on the shipping papers (i.e., "*RQ Radioactive Material, N.O.S., UN 2982*") and must be included in the package markings (Ref. **49 CFR 172.203(c)** and **49 CFR 172.324**).

- Shipping Papers **49 CFR 172.200-204**: General entries, description, additional description requirements, and shipper's certification.

  For most packages likely to be shipped by commercial radiopharmacies shipping papers are required. These must include:
  - proper shipping name (as described above);
  - hazard class of the material; for radioactive materials, the hazard class is 7;
  - identification number; for the proper shipping name, "*Radioactive Material, N.O.S.*", the identification number is UN 2982;
  - package type, which will usually be Type A;
  - name and quantity of each radionuclide in the shipment; the radionuclide may be abbreviated (i.e., Tc-99m);
  - physical and chemical form of the radioactive material;
  - category of label applied to each package in the shipment (i.e., "*Radioactive White-I*");
  - transport index (TI) of each package bearing Radioactive Yellow-II or Radioactive Yellow-III labels;
  - emergency response telephone number; and
  - shipper's certification and signature.

  Shipping papers may include additional information; however, the additional information must not detract from the required entries.

  For most, if not all, return shipments of wastes from radiopharmacy customers, the packages can be shipped as excepted packages (limited quantity of radioactive material) and will not require shipping papers; however, such shipments must include a statement on, in, or transported with, the package. The statement is contained in **49 CFR 173.422(a)(1)**, and must be verbatim. Although the proper preparation of the package of returned waste is the responsibility of the

shipper (i.e., the customer), radiopharmacies should be aware of the specific requirements if they intend to provide guidance to their customers regarding these types of shipments.

- Package Markings **49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324**: General marking requirements for non-bulk packaging, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging

  All certification packages shipped by commercial radiopharmacies (i.e., Type A packages) must be properly marked, as follows:
  - proper shipping name and identification number (i.e., "*Radioactive Material, N.O.S., UN 2982*");
  - the letters RQ if the packages contain a hazardous substance, which will only likely occur when the packages contain more than 10 millicuries of Iodine-131; and
  - the designation Type A, if the package conforms to the Type A requirements.

  DOT also specifies the size and appearance of the markings and markings that are prohibited.

- Package Labeling **49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440**: General labeling requirements, prohibited labeling, radioactive materials, placement of labels, specifications for radioactive labels.

  All packages routinely prepared and shipped by commercial radiopharmacies are required to be labeled in accordance with DOT regulations. The labels will usually be either "*Radioactive White-I*" or "*Radioactive Yellow-II*". Radiopharmacies have rarely offered a package labeled as "*Radioactive Yellow-III*" for shipment. Packages exhibiting surface radiation levels equal to or less than 0.5 millirem per hour will be labeled as "*Radioactive White-I*". There is no TI, defined as a unitless number equivalent to the radiation level, in millirems per hour, at one meter from the surface of the package, for a White-I label. Packages with surface radiation levels greater than 0.5 millirem per hour, but less than or equal to 50 millirems per hour, will be labeled with a Yellow-II label. The TI for a Yellow-II label must be less than or equal to 1. The lowest TI is 0.1, and all TIs are rounded to the nearest tenth.

  Packages required to be labeled must have two labels affixed, on opposite sides, but not on the top or bottom. The labels must include the identity and quantity of the radionuclides in the package. Yellow-II and Yellow-III labels must also include the TI. A label may not be affixed to a package that does not meet the applicable labeling requirements.

- Placarding of Vehicles **49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506,49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556**: Applicability, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, specifications for RADIOACTIVE placards.

  DOT regulations specify when vehicles carrying hazardous materials must be placarded. For radiopharmacy shipments, this is usually applicable only when packages with Yellow-III labels affixed are offered or transported. Since commercial radiopharmacies rarely, if ever, offer Yellow-III packages for transport, placarding of the vehicles is not of concern and will not be discussed in detail.

- Emergency Response Information, **Subpart G, 49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604**: Applicability and general requirements, emergency response information, emergency response telephone number.

  Persons, who offer hazardous materials for transport including radioactive materials, must provide or make available emergency response information, including:
  - An emergency response telephone number must be included on the shipping papers and the number must be monitored at all times that the material is being transported. The person monitoring the telephone number must be either knowledgeable of the hazardous material being shipped, or have comprehensive emergency response and incident mitigation information for that material, or have immediate access to a person who has such knowledge and information; and
  - Emergency response information for the shipment that will aid emergency responders in mitigating the consequences of an accident, including the health hazards of the material, handling fires and spills involving the material, and first aid measures must be included on, or with, the shipping papers.

  Applicants and licensees should review the specific DOT requirements applicable to emergency response information in the development of their programs and procedures.

- Training, **Subpart H, 49 CFR 172.700, 49 CFR 172.702; and 49 CFR 172.704**; Purpose and Scope, applicability and responsibility for training and testing, training requirements.

  Licensees who prepare packages of radioactive materials and who transport their own packages must provide training to their employees who perform those functions. The training must include:
  - General awareness and familiarization training designed to provide familiarity with DOT requirements, and enable the employee to recognize and identify hazardous materials;
  - Function-specific training concerning the DOT requirements which are specifically applicable to the functions the employee performs (i.e., if the employee's duties require him/her to affix DOT Radioactive labels to packages, he or she must receive training in DOT's regulations governing package labeling); and
  - Safety training concerning emergency response information, discussed above; measures to protect the employee and other employees from the hazards associated with the hazardous materials to which they may be exposed in the workplace; and methods of avoiding accidents, such as the proper procedures for handling packages containing hazardous materials.

  The training must be provided initially and then every three years. Records of training must be maintained.

- Shippers - General Requirements for Shipments and Packaging, **Subpart I, 49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.412, 49 CFR 173.415, 49 CFR 173.431, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.443, 49 CFR 173.448, 49 CFR 173.475**: Definitions, general design requirements, additional design requirements for Type A packages, authorized Type A packages, activity limits for Type A packages, requirements for determining A_1 and A_2, table of A_1 and A_2 values for radionuclides, radiation level limitations, contamination control, general transportation requirements, quality control requirements prior to each shipment.

- Carriage by Public Highway - General Information and Regulations, **Subpart A, 49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834, 49 CFR 177.842**: Driver training, shipping paper, general requirements (secured against movement), Class 7 (radioactive) material.

  Licensees who intend to transport their own packages must ensure that their drivers receive training in the safe operation of the vehicle transporting the hazardous material packages. The training requirements include, but are not limited to:
  - Pre-trip safety inspection of the vehicle;
  - Requirements pertaining to vehicle attendance and incident reporting; and
  - Loading and unloading of the materials, including blocking and bracing the packages and separation from occupied compartments.

  The specific training requirements are located in **49 CFR 177.816**.

  The licensee must also ensure that its drivers maintain the shipping papers accessible during transport and when the driver is not at the vehicle controls. During transport, the shipping papers must be located within the driver's reach while restrained by the lap belt -- either in a pocket in the driver's door of the vehicle or readily visible to someone entering the driver's compartment. In an accident, emergency responders are instructed to look in those locations for the shipping papers to aid in handling the hazardous material aspects, if any. Failure to properly locate shipping papers could adversely impact the response to an accident, result in actions that spread radioactive contamination, and result in unnecessary radiation exposures to the responders. When the driver is not at the vehicle controls, such as during deliveries to customers, the shipping papers for the packages remaining in the vehicle must be either in the pocket in the driver's side door or on the driver's seat in the vehicle.

  49 CFR 177.834(a) and 177.842 require that packages of radioactive materials be blocked and braced so that they cannot change position during conditions normally incident to transportation. The method used must prevent lateral movement of the packages during normal transport conditions (turns, curves, potholes, dips, stopping and acceleration, etc.). This does not include accident situations. The key test for evaluating the effectiveness of blocking and bracing is to attempt to move the package by hand after it is loaded. If the package can be moved through normal (non-Herculean) effort, then it is not properly blocked and braced. The use of a non-skid material on the vehicle surface where the package is loaded is not sufficient by itself. Additional means are necessary to block the package within the vehicle.

Package Activity Limits

Before offering a radioactive materials package for transport, the shipper must determine the category of the shipment. Licensees will likely prepare or transport two categories of packages containing radioactive material. The categories are based, in part, on the activity of the radioactive material contained in the package. The categories, activity ranges, packaging requirements, and examples are provided in **Table 8**. All quantities referenced here are multiples of the A_2 (normal form) values specified for radionuclides in **49 CFR 173.435** and the physical form is assumed to always be liquid.

Table 8: Package Activity Limits

Category	Activity Range	Packaging Requirements	Example
Excepted packages, limited quantity of radioactive material	Less than 10^{-4} A_2	**49 CFR 173.421 and 173.422**	Less than 21.6 millicuries of technetium-99m (usually for returned waste shipments)
Radioactive Material, N.O.S.	Greater than 10^{-4} A_2 but less than A_2	**Type A packaging (49 CFR 173.410; 49 CFR 173.412; 49 CFR 173.415; 49 CFR 173.431; 49 CFR 173.433)**	More than 21.6 millicuries, but less than 216 curies of technetium-99m

Once the quantity of material in the package has been determined, the appropriate packaging must be selected.

Packaging Design

Packages of radioactive material offered as excepted packages, limited quantity of radioactive material, in accordance with **49 CFR 173.421**, are required to meet the minimum packaging requirements of **49 CFR 173.410**. Those requirements primarily address, but are not limited to, maintaining package integrity and contents during conditions normally expected to occur during transport. This does not include survival during accidents. Packaging normally used by commercial radiopharmacies (i.e., military ammunition boxes, 'briefcases', and cardboard/fiberboard boxes, typically meet and exceed those minimal requirements).

Packages containing "*Type A*" quantities must meet more stringent criteria, including testing to demonstrate that the packages will maintain their integrity of containment and shielding during normal conditions of transport. The testing criteria for Type A packages are listed in **49 CFR 173.465**. Before offering a Type A package for shipment, the shipper is responsible for ensuring that the package has been tested to meet the criteria for the contents and the configuration to be shipped and maintaining a certificate of testing. Shippers are not required to personally test the packages, only to ensure that the testing was performed before use.

Quality Control

Prior to each shipment, the shipper is required to determine that the package is in condition for shipment. The determinations must include, but are not limited to verification of the following:

- Package is proper for the contents to be shipped;
- Packaging is in unimpaired physical condition; and
- External radiation and contamination levels are within the allowable limits.

The quality control requirements for radioactive material packages are located in **49 CFR 173.475**. The external radiation and contamination level limits are located in **49 CFR 173.441** and **173.443**. The applicant should ensure that its procedures for preparing radioactive material packages include provisions to survey the handle on ammunition boxes and briefcases used as packaging, in addition to the closure clasp on ammunition boxes. Excessive contamination has been identified in those locations in several package contamination events reported in the past.

Hazard Communications for Class 7 (Radioactive) Materials

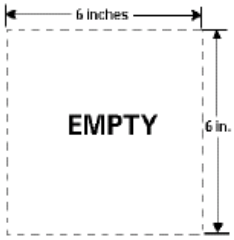
Labeling Packages (49 CFR 172.400-450)

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

Placement of Radioactive Labels

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

Determination of Required Label

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

Content on Radioactive Labels

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

Some Special Considerations/Exceptions for Labeling Requirements

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

Hazard Communications for Class 7 (Radioactive) Materials

Placarding Vehicles (49 CFR 172.500-560)

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

Visibility and Display of Radioactive Placard

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

Conditions Requiring Placarding

- Placards are required for any vehicle containing package with a RADIOACTIVE Yellow-III label
- Placards are required for shipment of LSA or SCO required by §173.427 to be consigned as exclusive use. Examples of this category are domestic, strong-tight containers with less than an A_2 quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52. Also, for bulk packages of these materials, the orange panel *marking* with the UN Identification number is not required.
- Placards are required any vehicle containing package with a Highway Route Controlled Quantity **(HRCQ)**. In this case, the placard must be placed in a square background as shown below (see §173.507(a))

Radioactive Placard

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

Some Special Considerations/Exceptions for Placarding Requirements

- Domestically, substitution of the UN ID number for the word "RADIOACTIVE" on the placard is prohibited for Class 7 materials. However, some import shipments may have this substitution in accordance with international regulations.
- Bulk packages require the orange, rectangular panel marking containing the UN ID number, which must be placed adjacent to the placard (see §172.332) [NOTE: except for LSA/ SCO exclusive use under §173.427, as above]
- If placarding for more than one hazard class, subsidiary placards must not display the hazard class number. Uranium Hexaflouride (UF_6) shipments ≥ 454 kg (1001 lbs) require both RADIOACTIVE and CORROSIVE (Class 8) placarding
- For shipments of radiography cameras in convenience overpacks, if the overpack does not require a RADIOACTIVE - YELLOW III label, vehicle placarding is not required (regardless of the label which must be placed on the camera)

Appendix N

Model Personnel Training Program

Training Program

1. General Instructions

   1.1. Training will be provided:
   - Before an employee assumes duties with, or in the immediate vicinity of, radioactive materials;
   - At least annually, as refresher training for all employees; and
   - Whenever a significant change occurs in duties, regulations, or the terms of a VDH license.

   1.2 Subjects covered for individuals working with, or in the vicinity of, radioactive materials or radiation:
   - Safe radiation practices associated with the job (examples of topics that may be covered are found in Section 3 of this Appendix);
   - Site-specific radiation safety practices; and
   - Applicable VDH rule.

   1.3 Subjects covered for ancillary personnel:
   - Significance of the radiation symbol and its use on signs and labels;
   - Location of unrestricted areas; and
   - Whether the individual is authorized access to the restricted areas of the pharmacy.

   1.4. Type of instruction:
   - Instruction in the licensee's site-specific radiation safety program and VDH regulatory requirements may be in the form of lecture, demonstrations, videotape, or self study, and should emphasize practical subjects important to the safe use of radioactive material; and
   - Individuals receiving instructions should be provided an opportunity to ask questions.

2. Instruction for individuals likely to receive an occupational dose in excess of 100 mSv (100 mrem)

   2.1 Instruction will be provided:
   - Before an employee assumes duties with or in the immediate vicinity of radioactive materials;
   - At least annually, as refresher training; and
   - Whenever a significant change occurs in duties, rules, or terms of VDH license.

   2.2 Licensee must provide instruction in subjects covered in **12VAC5-481-2270**

   2.3 Records of initial and refresher training should be maintained and should include:
   - Name of the individual who provided the instruction;
   - Names of the individuals who received the instruction; and
   - Date of instruction and list of topics covered.

3. Suggested radiation safety training topics for individuals working with, or in the vicinity of, radioactive material (this section is intended as a guide to topics covered in a typical radiation safety training program; topics selected should be commensurate with the individuals' duties).

   3.1 Basic radiation safety information:
   - Basic radiation biology (e.g., interaction of ionizing radiation with cells and tissues);
   - Radiation safety
     - Radiation vs. contamination
     - Internal vs. external exposure;
     - Biological effects of radiation;
     - ALARA concept; and
     - Use of time, distance, and shielding to minimize exposure;
   - Risk estimates, including comparison with other health risks (**12VAC5-481-2270**);
   - Regulatory requirements;
     - RSO;

- Material control and accountability;
- Dose to individual members of the public;
- Personnel dosimetry;
- Occupational dose limits and their significance;
- Dose limits to the embryo/fetus, including instruction on declaration of pregnancy;
- Workers' right to be informed of occupational radiation exposure;
- Radiation safety program audits;
- Ordering and receipt of packages;
- Transfer;
- Waste disposal;
- Recordkeeping;
- Surveys;
- Postings;
- Labeling of containers;
- Handling and reporting of incidents or events;
- Licensing and inspection by VDH;
- Need for complete and accurate information;
- Employee protection; and
- Deliberate misconduct

3.2. General topics for safe use of radioisotopes:

- Wear a laboratory coat or other protective clothing at all times when working with radioactive materials;
- Use syringe shields and vial shields when preparing and handling radioactive drugs;
- Measure all radiopharmaceuticals prior to transfer;
- Measure the molybedenum-99 content of each generator elution and do not transfer those radiopharmaceuticals for human medical use that will contain more then 0.15 microcuries of molybedenum-99 per mCi of technetium-99m at the time of administration;
- Wear disposable gloves at all times when handling radioactive materials and change gloves frequently to minimize the spread of contamination;
- Before leaving the hot lab, monitor hands, shoes, and clothing for contamination in a low-background area, allowing sufficient time for instrument response;
- Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used;
- Do not store food, drink, or personal effects in areas where radioactive material is stored or used. Personnel items brought into the restricted area (i.e., radios, compact discs, notepads, books, etc.) should be surveyed for contamination before removal from the area;
- Food and beverages used in the preparation of radiopharmaceuticals should be clearly labeled "*Not for personal consumption*" if stored with radioactive materials;
- Wear personnel monitoring devices, if required, at all times while in areas where radioactive material is used or stored;
- Dispose of radioactive waste only in designated, labeled and properly shielded receptacles;
- Never pipette by mouth;
- Store radioactive solutions in clearly labeled containers; and
- Secure all radioactive material when it is not under the constant surveillance and immediate control of the user(s).

3.3. Instruction on radiopharmacy-specific program elements:

- Applicable rules and license conditions;
- Areas where radioactive material is used or stored;

- Potential hazards associated with radioactive material in each area where the individuals will work;
- Special procedures for handling volatile materials;
- Proper use of radiation shielding;
- Proper use of survey and analytical instruments;
- Appropriate response to spills, emergencies, or other unsafe conditions;
- Emergency procedures;
- Previous incidents, events, and/or accidents;
- Survey program;
- Effluent monitoring and control;
- Customer-returned waste pickup, receipt, and handling;
- Waste management and minimization;
- Personnel monitoring;
- Procedures for receiving packages containing radioactive materials;
- Procedures for opening packages;
- Sealed sources and leak tests; and
- Other topics, as applicable.

Appendix O:

Model Dose Calibrator Testing Program

Model Procedures for Testing Dose Calibrators Used to Measure Photon-emitting Radionuclides

This model procedure can be used by applicants and licensees for checking and testing done calibrators.

1. Test for the following at the indicated frequency. Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances.
   1.1. Constancy, at least once each day prior to assay of patient dosages (a safe margin is considered to be below $\pm 10\%$).
   1.2. Linearity at installation and at least quarterly thereafter (a safe margin is considered to be below $\pm 10\%$).
   1.3. Geometry dependence at installation (a safe margin is considered to be below $\pm 10\%$).
   1.4. Accuracy, at installation and at least annually thereafter (a safe margin is considered to be below $\pm 10\%$).
2. After repair, adjustment, or relocation of the dose calibrator, such that proper function of the ionization chamber or electronics would likely be in doubt, repeat the above tests as appropriate.
3. Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cesium-137, Cobalt-60, Cobalt-57, or Radium-226 using a reproducible geometry each day before using the calibrator; consider using two or more sources with different photon energies and activities.
   Use the following procedure:
   3.1. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cesium 137 setting to assay Cesium-137).
   3.2. Measure background at the same setting and subtract or confirm the proper operation of the automatic background circuit if it is used.
   3.3. For each source used either plot or log (i.e., record in the dose calibrator log book) the background level for each setting checked and the net activity of each constancy source.
   3.4. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
   3.5. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the authorized nuclear pharmacist or the radiation safety officer of a suspected malfunction of the calibrator. These action levels should be written in the log book or posted on the calibrator. The dose calibrator should be repaired or replaced if the error exceeds 10%.
4. The linearity of a dose calibrator should be ascertained over the range of its use between the maximum activity in a vial and 30 microcuries. Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This example uses a vial of Technetium-99m that has the anticipated maximum activity to be assayed (e.g., the first elution from a new generator) and assumes your predetermined safety margin is $\pm 5\%$.
   4.1. Time Decay Method
      4.1.1. Inspect the instrument to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).
      4.1.2. Assay the Technetium-99m vial in the dose calibrator and subtract background to obtain net activity in millicuries.
      4.1.3. Repeat step 4.1.2. at time intervals of 6, 24, 30, and 48 hours after the initial assay.
      4.1.4. Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

Assay Time[4] (hours)	Correction Factor
0	31.6
6	15.8
24	2.00
30	1.00
48	0.126

[4] Assay times should be measured in whole hours and correction factors should be used to three significant figures as indicated. The half-life of $T_{1/2}$ = 6.02 hours has been used in calculating these correction factors.

Example: If the net activity measured at 30 hours was 15.6 mCi, the calculated activities for 6 and 48 hours would be 15.6 X 15.9 = 248 mCi and 15.6 mCi X 0.126 = 1.97 mCi, respectively.

4.1.5. Plot both the measured net activity and the calculated activity versus time.

4.1.6. On the graph, the measured net activity plotted should be within $\pm 5\%$ of the calculated activity if the instrument is linear and functioning properly. If variations greater than 5% are noted, adjust the instrument, have it repaired, or use arithmetic correction factors to correct the readings obtained in daily operations.

4.2 Shield Method: If a set of "sleeves" of various thicknesses are used to test for linearity, it will first be necessary to calibrate them.

4.1.1 Begin the linearity test by assaying the Technetium-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date and time to the nearest minute, and net activity. This first assay should be done in the morning at a regular time. After making the first assay, the sleeves can be calibrated as follows (steps 4.2.2. through 4.2.4 must be completed within 6 minutes).

4.1.2 Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

4.1.3 Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

4.1.4 Continue for all sleeves.

4.1.5 Complete the following decay method linearity test steps:

4.1.5.1 Repeat the assay at about noon, and again at about 4:00 p.m. Continue on subsequent days until the assayed activity is less than 30 millicuries. For dose calibrators on which the range is selected with a switch, select the range normally used for the measurement.

4.1.5.2 Convert the time and date information recorded to hours elapsed since the first assay.

4.1.5.3 On a sheet of semilog graph paper, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Plot the data.

4.1.5.4 Draw a 'best fit' straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.
(A-observed) – (A-line) / (A-line) = deviation.

4.1.5.5 If the worst deviation is more than ± 0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph.

4.1.6 From the graph made in step 4.2.5.3, find the decay time associated with the activity indicated with sleeve 1 in place. This is the 'equivalent decay time' for sleeve 1. Record that time with the data received in step 4.2.2.

4.1.7 Find the decay time associated with the activity indicated with sleeve 2 in place. This is the 'equivalent decay time' for sleeve 2. Record that time with the data received in step 4.2.3.

4.1.8 Continue for all sleeves.

4.1.9 The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

4.1.10 Assay the Technetium-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the net activity.

4.1.11 Steps 4.2.12 through 4.2.14 below must be completed within 6 minutes.

4.1.12 Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

4.1.13 Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

4.1.14 Continue for all sleeves.

4.1.15 On a sheet of semilog graph paper, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the model number and serial number of the dose calibrator.

4.1.16 Plot the data using the equivalent decay time associated with each sleeve.

4.1.17 Draw a 'best fit' straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.
(A-observed) – (A-line) / (A-line) = deviation.

4.1.18 If the worst deviation is more than ± 0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow conversion from activity indicated by the dose calibrator to 'true activity'.

5. Geometry independence means that the indicated activity does not change with volume or configuration. The test for geometry independence should be conducted using syringes and vials that are representative of the entire range of size, shape, and constructions normally used for injections and a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following examples assumes that injections are done with 3-cc plastic syringes, that radiopharmaceutical kits are made in 30-cc glass vials, and that the predetermined safety margin is $\pm 5\%$.

5.1 In a small beaker or vial, mix 2 cc of a solution of Technetium-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second beaker or vial with nonradioactive saline. Tap water may be used.

5.1 Draw 0.5 cc of the Technetium-99m solution into the syringe and assay it. Record the volume and millicuries.

5.2 Remove the syringe from the calibrator, draw an additional 0.5 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

5.3 Repeat the process until a volume of 2.0 cc has been assayed. The entire process must be completed within 10 minutes.

5.4 Select as a standard the volume closest to that normally used for injections. For all other volumes, divide the standard millicuries by the millicuries indicated for each volume. The

quotient is a volume correction factor. Alternatively, graph the data and draw horizontal error lines above and below the chosen 'standard volume'.

5.5 If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the error lines, it will be necessary to make a correction table or graph that will allow a conversion from 'indicated activity' to 'true activity'. If this is necessary, be sure to label the table or graph 'syringe geometry dependence', and note the date of the test and model and serial number of the calibrator.

5.6 To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Technetium-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.

5.7 Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

5.8 Repeat the process until a volume of 19.0-cc has been assayed. The entire process must be completed within 10 minutes.

5.9 Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, the data may be graphed, with horizontal 5% error lines drawn above and below the chosen 'standard volume'.

5.10 If any correction factors are greater than 1.05, or less than 0.95, or if any data points lie outside the 5% error lines, it will be necessary to make a correction table or graph that will allow conversion from 'indicated value' to 'true activity'. If this is necessary, be sure to label the table or graph 'vial geometry dependence', and note the date of the test and the model number and serial number of the calibrator.

6. Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Institute of Standards and Technology (NIST) or by the supplier who has compared that source to a source that was calibrated by NIST. Certified sources are available from NIST and from many radioisotope suppliers. At least two sources with different principal photon energies (such as Cobalt-57, Cobalt-60, Cesium-137) should be used. One source should have a principal photon energy between 100keV and 500keV. If a Radium-226 source is used it should be at least 10 microcuries, other sources should be at least 50 microcuries. Consider using at least one reference source whose activity is within the range of activities normally assayed.

6.1 Assay a calibrated reference source at the appropriate setting (i.e., use the Cobalt-57 setting to assay Cobalt-57) and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for a total of three determinations.

6.2 Average the three determinations. The average value should be within the predetermined safety margin, which in this example is 5% of the certified activity of the reference source, mathematically corrected for decay.

6.3 Repeat the procedure for other calibrated reference sources.

6.4 If the average value does not agree, within 5%, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The dose calibrator should be repaired or replaced if the error exceeds 10%.

6.5 At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values with the accuracy data.

6.6 Put a sticker on the dose calibrator noting when the next accuracy test is due.

7. The individual performing the tests will sign or initial the records of geometry, linearity, and accuracy tests.

Appendix P:

Material Receipt and Accountability

Sample Model Procedure for Ordering and Receiving Radioactive Material

- The RSO should approve or place all orders for radioactive material and should ensure that the requested material, quantities, manufacturer, and model are authorized by the license and that the possession limits are not exceeded.
- Carriers should be instructed to deliver radioactive packages directly to the designated receiving area.

Sample Instructions to Personnel Involved in Material Receipt

Shipping and Receiving Personnel

During normal working hours, within 3 hours of receipt of any package of radioactive material, each package must be visually inspected for any signs of shipping damage, such as crushed or punctured containers or signs of dampness. Any suspected damage must be reported to the RSO immediately. Do not touch any package suspected of leaking. Request the person delivering the package, if still on site, to remain until monitored by the RSO.

Outside of normal working hours (e.g., nights, weekends, and holidays), deliveries may be made to a designated, secured storage area. These packages must be checked for contamination and external radiation levels within 3 hours after personnel arrive at the facility. They should not be allowed to remain in the designated storage area any longer than necessary, as they may be a source of exposure for pharmacy personnel.

Sample Model Procedure for Safely Opening Packages Containing Radioactive Materials

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

- Wear gloves to prevent hand contamination;
- Visually inspect the package for any sign of damage (e.g., crushed, punctured). If damage is noted, stop and notify the RSO;
- Check DOT White I, Yellow II, or Yellow III label or packing slip for activity of contents to ensure that the shipment does not exceed license possession limits;
- Monitor the external surfaces of a labeled package according to specifications in **Table 1**;
- Open the outer package (following supplier's directions if provided) and remove packing slip. Open inner package to verify contents, comparing requisition, packing slip, and label on the container. Check integrity of the final source container (e.g., inspecting for breakage of seals or vials, loss of liquid, discoloration of packaging material, high count rate on smear). Again check that the shipment does not exceed license possession limits. If anything other than the expected observation is identified, stop and notify the RSO;
- Survey the packing material and packages for contamination before discarding. If contamination is found, treat as radioactive waste. If no contamination is found, obliterate the radiation labels prior to discarding in the regular trash;
- Maintain records of receipt, package survey, and wipe test results; and
- Notify the final carrier and VDH when removable radioactive surface contamination exceeds the limits of 22 disintegrations per minute per square centimeter (dpm/cm^2) averaged over 300 cm^2 (6600 dpm / 300 square centimeters); or external radiation levels exceed 2.0 mSv/hr (200 mrem/hr) at the surface.

Appendix Q:

General Topics for Safe Use of Radioisotopes and Model Emergency Procedures

General Topics for Safe Use of Radioisotopes

Each licensee using radioactive material should establish general rules for the safe use of the material so that workers know what is required. Typical instructions should include:

- Wear a laboratory coat or other protective clothing at all times when working with radioactive materials;
- Use syringe shields and vial shields when preparing and handling radioactive drugs;
- Measure all radiopharmaceuticals prior to transfer;
- Measure the molybdenum-99 content of each generator elution and do not transfer those radiopharmaceuticals for human medical use that will contain more than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m at the time of administration;
- Wear disposable gloves at all times when handling radioactive materials and change gloves frequently to minimize the spread of contamination;
- Before leaving the hot lab, monitor hands, shoes, and clothing for contamination in a low-background area, allowing sufficient time for instrument response;
- Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used;
- Do not store food, drink, or personal effects in areas where radioactive material is stored or used. Personal items brought into the restricted area (i.e., radios, compact discs, notepads, books, etc.) should be surveyed for contamination before removal from the area;
- Food and beverages used in the preparation of radiopharmaceuticals should be clearly labeled "*Not for personal consumption*" if stored with radioactive materials;
- Wear personnel monitoring devices, if required, at all times while in areas where licensed materials are used or stored;
- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles;
- Never pipette by mouth;
- Store radioactive solutions in clearly labeled containers; and
- Secure all radioactive material when it is not under the constant surveillance and immediate control of the user(s).

Model Procedures for Handling Millicurie Quantities of Radioiodine

Due to the potential for significant intakes, due to volatility and accidental ingestion, and skin exposures (SDE) from contamination, licensees should establish specific procedures for the containment and handling of millicurie quantities of radioiodine, most commonly Iodine-131. The following guidance is the minimum that should be considered if the applicant intends to manipulate radioiodine:

- Manipulation of radioiodine (e.g., handling or compounding capsules, performing radioiodination, dispensing from bulk solution) should be conducted in an isolated area within the main hot lab of the pharmacy. This will aid in maintaining exposures ALARA and provide a means to isolate the area in the event of a spill;
- Radioiodine handling should only be performed inside a glovebox or fume hood. The ventilation for gloveboxes and fume hoods should be checked at least once every six months to ensure adequate airflow and confirm negative pressure with respect to the area around the glovebox or fume hood. Exhaust stacks for gloveboxes and fume hoods used for handling radioiodine should not be located near ventilation intakes to minimize the likelihood of recirculation to the pharmacy or to other tenants in a shared building;
- Gloveboxes and fume hoods must include appropriate filters (activated charcoal) to minimize effluents from radioiodine handling;
- Filters must be installed and used in accordance with the manufacturer's specifications (e.g., adequate air flow to ensure adequate residence time);

- Filters should be checked at installation and periodically, based on use, but not less than once per calendar quarter, to ensure continued efficiency;
- Air flow through fume hoods and gloveboxes should be confirmed before each use;
- Magna-helic sensors, if used, should be checked before each use of the glovebox or fume hood, to ensure minimum flow across the filter;
- Absorbent materials and dry chemical buffers, for use in the event of a spill, should be located near the area where millicurie quantities of radioiodine are handled;
- Additional protective clothing should be used when handling millicurie quantities of radioiodine. Personnel should be double gloved and use shoulder-length sleeve guards. The gloves and glove seals on gloveboxes should be checked periodically and replaced when needed; and
- All personnel handling greater than 500 millicuries of Iodine-131 in a year should be considered for bioassay. This is the threshold below which intakes over 1% of the annual limit on intake (ALI) are not likely and assumes no containment. When used in a properly operating fume hood, the threshold for consideration of the need for bioassay rises to 5 curies of Iodine-131. If used in a properly operating glovebox, with properly sealed glove ports and well maintained gloves, the threshold rises to 50 curies of Iodine-131 handled by one person per year. Pharmacies using gloveboxes that do not have sealed glove ports may not use the threshold indicated for that equipment, but may use the threshold for properly maintained fume hoods.

Model Procedures for Handling Events

Suggested Thresholds for Defining Minor Contamination Events, Minor Spills, and Major Spills

Licensees should establish clearly delineated thresholds for describing these types of events. Licensees should establish a graded response to emergencies, incorporating increasing formality of a response based on the potential risks posed by the events. No emergency procedure can anticipate every likely event; therefore, flexibility and judgment must be incorporated into such procedures. Most importantly, if licensee staff are not sure of the proper or expected response to any event, no matter how minor, they should be instructed to immediately cease further action, control access to the area, contact the RSO, and wait for instructions.

Although the following is only suggested guidance for establishing response thresholds, significant deviations in actual licensee emergency procedures should be clearly justified.

Minor Contamination Events

Those events typically identified through routine surveys that involve removable contamination levels greater than the licensee's action limit, but less than ten times the licensee's action limit. Minor contamination events can be easily decontaminated without the need for strict adherence to a step-by-step procedure. Such events require judgment on the part of the individual responding to determine the scope and extent of the contamination and to assess their ability to respond effectively. In order to prevent the spread of contamination, coworkers should be notified if decontamination of the area will be delayed. The RSO should be notified promptly of such events, either before, or immediately after, cleanup of the area. Isolated minor contamination events may not require a formal root cause evaluation or extensive corrective action determinations; however, several events in the same location, involving the same individual, or during similar processes may warrant such in-depth evaluations and determinations.

Minor Spills

Those events typically identified at the time they occur (i.e., a dropped syringe or vial containing radioactive material) involving the release (spill) of radioactive material requiring a more formal adherence to a step-by-step procedure. Such events will usually involve millicurie quantities of material and have a potential for exposures to personnel or the public if not properly controlled and decontaminated. The upper limit for defining minor spills should not be more than five times the lowest annual limit on intake (ALI) of the material involved in the spill. Such a limit would include the following quantities of radioactive material:

1. Up to 400 millicuries of Technetium-99m;
2. Up to 150 microcuries of Iodine-131;
3. Up to 100 millicuries of Thallium-201; and
4. Up to 10 millicuries of Samarium-153.

Minor spills may warrant root cause evaluations and corrective action determinations, depending on the circumstances. The RSO should be notified immediately of such events so that decontamination procedures can be monitored. Minor spills involving quantities of radioactive material near the upper threshold may require more than one person to respond to assist in the cleanup, perform confirmation surveys, or monitor materials and personnel exiting the area.

Major Spills

Any spill involving a quantity of radioactive material in excess of the quantity defined for a minor spill is considered a major spill. Such spills have a greater potential for exposures to workers and the public, including the possibility of overexposure, if not properly contained. Individuals should never attempt to clean a major spill by themselves, or without the personal supervision and direction of the RSO. Major spills should generally be reported to VDH in accordance with the requirements of **12VAC5-481-1110**. Major spills may also require evaluations of intakes and skin doses, if personnel contamination is identified, as well as root cause evaluations and corrective action determinations. Qualified assistance should be sought immediately for those major spills that are beyond the licensee's capability to address.

General Safety Procedures to Handle Spills

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

Minor Contaminations and Spills of Liquids and Solids

- Instructions to Workers
  - These instructions apply to minor contamination events (less than 10 times the licensee's action limit) and minor spills of radioactive material. The response to each is similar; however, the response to minor contamination events need not be as formal as the response to spills involving millicurie quantities of radioactive material.
  - Notify persons in the area that a spill has occurred;
  - Prevent the spread of contamination by covering the spill with absorbent paper. Paper should be dampened if solids are spilled;
  - Clean up the spill, wearing disposable gloves and using absorbent paper;
  - Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Put contaminated gloves and other contaminated disposable material in the bag;
  - Resurvey the area. Check the area around the spill for contamination. Also check hands, clothing, and shoes for contamination; and
  - Report the incident to the Radiation Safety Officer (RSO) promptly.

- Reminders to RSO
  - Follow up on the decontamination activities and document the results;
  - As appropriate, determine cause and corrective actions needed;
  - Consider bioassays if radioactive material may have been ingested or inhaled;
  - Consider performing a determination for the dose to the members of the public if radioactive material may have exceeded the constraint on airborne emissions; and
  - If necessary, notify VDH.

Major Spills of Liquids and Solids

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

- Reminders to RSO
  - Confirm decontamination of personnel. If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration;

- Skin contamination must be evaluated to determine potential exposures. Beta-emitting radionuclides have a high potential for resulting in shallow-dose exposures in excess of regulatory limits from small (microcurie) quantities of contamination;
- Supervise decontamination activities and document the results. Documentation should include location and results of surveys and decontamination results;
- Determine root cause and needed corrective actions;
- Consider need for bioassays if radioactive material may have been ingested, inhaled, or absorbed;
- Consider need for performing a determination of the dose for members of the public if radioactive material may have exceeded the constraint on airborne emissions; and
- If necessary, notify VDH.

Minor Fires

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

- Reminders to RSO
  - Notify emergency medical personnel of any injured individuals who may be contaminated. Provide radiation safety assistance (e.g., monitoring) as needed or requested.
  - Supervise decontamination activities at the facility;
  - If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove contamination that was released by the perspiration;
  - Consult with fire safety officials to ensure that there is no likelihood of fire restarting;
  - Determine cause and needed corrective actions; consider need for bioassays if radioactive material may have been ingested or inhaled. Document incident; and
  - If necessary, notify VDH.

Fires, Explosions, or Major Emergencies

- Instructions to Workers
  - Notify all persons in the area to leave immediately;
  - Notify the fire department;
  - Notify the RSO and other facility safety personnel;
  - Ensure injured personnel receive medical attention;

- Upon arrival of firefighters, inform them where radioactive material are stored and where radioisotopes were being used; inform them of the present location of the radioactive material and the best possible entrance route to the radiation area, as well as any precautions to avoid exposure or risk of creating radioactive contamination by use of high pressure water, etc;
- Allow no one to return to work in the area unless approved by the RSO; and
- Follow the instructions of the RSO (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO
  - Notify emergency medical personnel of any injured individuals who may be contaminated. Provide radiation safety assistance (e.g., monitoring) as needed or requested;
  - Coordinate activities with local fire department;
  - Consult with the firefighting personnel and set up a controlled area where the firefighters can be surveyed for contamination of their protective clothing and equipment after fire is extinguished;
  - Once the fire is extinguished, provide assistance to firefighters who may need to re-enter restricted areas to determine the extent of the damage to the radioactive material use or storage areas. To the extent practical, assist firefighters in maintaining their exposures ALARA if the fire resulted in a significant release of radioactive material or lost of shielding capability, such that excessive radiation levels (greater then 100 millirems per hour) are created;
  - Perform thorough contamination surveys of firefighters and their equipment before they leave the controlled area and decontaminate, if necessary;
  - Supervise decontamination activities;
  - Consider bioassays if radioactive material may have been ingested or inhaled. Document incident;
  - Consider performing a determination for the dose to members of the public if radioactive material may have exceeded the constraint on airborne emissions; and
  - If necessary, notify VDH

Note: Copies of emergency procedures should be provided to all users. A current copy of the emergency procedure should be posted in each area where radioactive material is used.

Appendix R:

Radiation Survey Procedures

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

Ambient Radiation Level Surveys

- Dose-rate surveys, at a minimum, should be performed in locations where workers are exposed to radiation levels that might result in radiation doses in excess of 10% of the occupational dose limits.
- Dose-rate surveys, at a minimum, should be performed in locations where members of the public could receive a total effective dose equivalent of 1 mSv (100 mrem) in a year, or the dose in any unrestricted area from external sources could exceed 0.02 mSv (2 mrem) in any one hour.
- Dose-rate surveys should be performed in a manner and frequency that is representative of the use of radioactive materials. At a minimum, these surveys should be conducted daily in areas of radioactive material use, where exposures to workers could reasonably occur (e.g. generator storage/elution and dose preparation stations). Other areas, where radiological conditions are not expected to change appreciably from day-to-day, should be surveyed weekly (e.g. radioactive waste storage areas).

Contamination Surveys

Licensees' contamination surveys should be sufficient to identify areas of contamination that might result in unacceptable levels of exposure to workers or to the public. Combined removable and fixed contamination should be surveyed using appropriate radiation detection equipment. Removable contamination can be detected and measured through wipe tests, which should be analyzed using an appropriate counting instrument. Fixed contamination may be measured directly at the surface of the contamination with the appropriate instrument detector held at close proximity to the surface without direct contact. See **Table 6** in **Appendix J** for examples of appropriate instruments.

Contamination surveys should be performed:

- To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, or equipment;
- After any spill or contamination event;
- To evaluate contamination of users and the immediate work area at the end of each day when radioactive material is used;
- In unrestricted areas at frequencies consistent with the types and quantities of materials in use;
- In areas adjacent to restricted areas and in all areas through which radioactive materials are transferred and temporarily stored before shipment.

Contamination Survey Frequency

All areas where radioactive materials are eluted, prepared, assayed, dispensed, or packaged for transport should be surveyed daily. All other areas where radioactive materials are used or stored should be surveyed weekly.

Contamination in Unrestricted Areas

Contamination found in unrestricted areas should be immediately decontaminated to background levels. When it is not possible to get to background levels, the licensee must ensure that the amounts do not exceed the contamination levels listed in **Table 9.**

Table 9: Recommended Action Levels in dpm/100 cm^2 for Removable Surface Contamination by Radiopharmaceuticals

	P-32, Se-75, Sr-85, Sr-89, In-111, I-123, I-125, I-131, Sm-153, Yb-169, Re-186, Au-198	Cr-51, Ga-67, Tc-99m, Tl-201
1. Unrestricted areas, personal clothing	200	2000
2. Restricted areas, protective clothing used only in restricted areas, skin	2000	20000

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

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

Survey Record Requirements

Each survey report should include the following:

- Diagram of the area identifying specific locations surveyed (See **Figure 1**, located in **Item 13**);
- Ambient radiation levels with appropriate units;
- Contamination levels with appropriate units;
- Make and model number of instruments used;
- Background levels;
- Name of the person making the evaluation and recording the results and date; and
- Corrective actions taken for elevated levels identified and results of resurveys.

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

Air Sampling

Air sampling can be used to do the following:

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

Refer to NRC Regulatory Guide 8.25, Revision 1, ‘Air Sampling in the Workplace’, and NRC NUREG - 1400, ‘Air Sampling in the Workplace’, for further guidance on air sampling, which are available at the NRC website, www.nrc.gov.

Air Stack Release Monitoring

Airborne radioactive effluents should be monitored at the release points (e.g., stack) to provide accurate measurements to estimate public exposure. Licensees should verify the performance of effluent monitoring systems by regular calibration of equipment and checks of filtration to ensure their reliability.

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

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

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

Radioiodine Monitoring

The handling of radioiodine requires additional surveys and monitoring. Such surveys and monitoring include:

- Routine surveys should be performed of air filters incorporated in fume hoods and gloveboxes to identify when filters should be exchanged prior to saturation;
- Routine surveys should be performed in the area where radioiodine is handled immediately following each use to identify elevated radiation and contamination levels; and
- Continuous monitoring of the air effluent should be performed during radioiodine use. In-line filters should be monitored periodically to determine actual effluents.

Sanitary Sewerage Release Monitoring

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

Bioassay Monitoring

Frequency of Required Bioassay Measurements

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

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

Bioassay measurements used for demonstrating compliance with the occupational dose limits should be conducted often enough to identify and quantify potential exposures and resultant intakes that, during any year, are likely to collectively exceed 0.1 times the ALI. The 10% ALI criterion is consistent with

12VAC5-481-760, which requires licensees to monitor intakes and assess occupational doses for exposed individuals who are likely to exceed 10% of the applicable limit (i.e., intakes likely to exceed 0.1 ALI for adults).

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

Routine Measurements

Routine measurements include baseline measurements, periodic measurements, and termination measurements. These measurements should be conducted to confirm that appropriate controls exist and to assess dose.

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

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

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

Special Monitoring

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

- Presence of unusually high levels of facial and/or nasal contamination;
- Operational events with a reasonable likelihood that a worker was exposed to unknown quantities of airborne radioactive material (e.g., loss of system or container integrity);
- Known or suspected incidents of a worker ingesting radioactive material; and
- Incidents that result in contamination of wounds or other skin absorption.

References:

1. NRC Regulatory Guide 4.20, ‘Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors’.
2. NRC Regulatory Guide 8.9, Revision 1, ‘Acceptable Concepts, Models, Equations , and Assumptions for a Bioassay Program’.
3. NRC Regulatory Guide 8.25, Revision 1, ‘Air Sampling in the Workplace’.
4. NRC Regulatory Guide 8.37, ‘ALARA Levels for Effluents from Materials Facilities’.

5. NRC NUREG-1400, ‘Air Sampling in the Workplace’.
6. NRC NUREG/CR-4884, ‘Interpretation of Bioassay Measurements’.
7. ANSI N13.1 (1969), ‘Document to Sampling Airborne Radioactive Materials in Nuclear Facilities’.
8. ANSI N42.18, ‘Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents’.

These can be accessed at the NRC’s website, www.nrc.gov or by contacting VDH.

Appendix S:

Procedure for Return of Radioactive Wastes from Customers

Return only items that contained or contain radioactive materials supplied by the radiopharmacy (e.g., pharmacy-supplied syringes and vials and their contents). Most return shipments to radiopharmacies will qualify as excepted packages of limited quantity, in accordance with DOT requirements (**49 CFR 173.421**). For those packages containing radioactive material in excess of the limited quantity, customers should ensure that all applicable DOT requirements are met for the packages. This includes, but is not limited to, certification packaging (Type A), package marking and labeling, and shipping papers. For specific guidance on preparing these types of packages, please follow your in-house procedures for shipping radioactive material packages or contact the pharmacy for guidance.

Preparation of radioactive materials for return as excepted package of limited quantity:

- Ensure that the activities of material being returned are limited quantities as defined by DOT (see table below). Special attention should be given for the return of unused doses that may still contain significant activities of radionuclides. The amount of radioactivity in unused doses may necessitate that a syringe or vial be held for decay to reduce the activity to that permitted for shipment of limited quantities.
- Place the syringe or vial in the original, labeled, lead shield in which it was delivered; and
- Place shielded waste into the shipping package (e.g., padded briefcase or ammo box) in which it was delivered.

Note: Packages used to ship radioactive material to customers must meet the DOT package requirements for transport of limited quantities.

Preparation of package:

- Using a calibrated survey meter, measure the radiation levels at all points on the surface of the package to ensure that levels are less than or equal to 0.5 mrem/hr;
- Use contamination wipes on the surface of the package to ensure that the removable contamination does not exceed the limit specified in **49 CFR 173.443(a) -** 22 dpm/cm^2 over a 300 cm^2 area;
- Label the package as a "*Excepted Package - Limited Quantity of Material*"; and
- Seal the package so that it will be evident upon receipt whether the package accidentally opened during shipment.

Note: Shipping papers are not required when shipping limited quantities however, the statement specified in **49 CFR 173.422** ("*This package conforms to the conditions and limitations specified in **49 CFR 173.421** for radioactive material, excepted package-limited quantity of material, UN2910.*") must be included in, on, or otherwise provided with the shipment.

Limited Quantities (49 CFR 173.421) For Typical Radionuclides as Liquid Used by Radiopharmacies (49 CFR 173.425)

Table 10: Limited Quantity Values for Liquid Radioactive Material Packages

Radionuclide – Liquids	A2 Value	Limited Quantity Shipment (mCi) A2 X 10^{-4}
Co-57	216	21.6
Co-58	27	2.7
Cr-51	811	81.1
Ga-67	162	16.2
I-123	162	16.2
I-125	54.1	5.41
I-131	13.5	1.35
In-111	54.1	5.41
Mo-99	20 (for domestic use)	2
P-32	8.11	0.81
Se-75	81.1	8.1
Sr-89	13.5	1.35
Tc-99m	216	21.6
Tl-201	270	27

Table 11: Limited Quantity Values for Gaseous Radioactive Material Packages

Radionuclide Uncompressed Gas	A2 Value (Ci)	Limited Quantity Shipment (mCi) A2 X 10^{-3}
Xe-133 (uncompressed)	541	541

Table 12: Limited Quantity Values for Special Form Radioactive Material Packages

Radionuclide Solid – Special Form	A1 Value (Ci)	Limited Quantity Shipment (mCi) A1 X 10^{-3}
Ir-192	27	27
Cs-137	54.1	54.1

The values above are derived from **49 CFR 173.423**, **Table 8**, and the Table of A1 and A2 values for radionuclides in **49 CFR 173.435**. If shipping more than one radionuclide in the same package, the limits in **49 CFR 173.433(d)** apply as follows:

- The sum of the ratios of the activity of each radionuclide divided by its respective A2 value must be less than, or equal to, one. For special form material, the sum of the ratios of the activities of each radionuclide divided by its respective A1 value must be less than, or equal to, one.

Procedure for Driver or Courier for Pick-up of Radioactive Waste from Customers

- Ensure that the shipping package is properly labeled "*Excepted Package - Limited Quantity of Material*";
- Ensure that the shipping package has been sealed; and
- Do not accept any package that is not properly labeled and sealed.

Procedure for Receipt and Opening of Packages from Customers Containing Radioactive Waste

- Place all returned packages in an identifiable location within the radiopharmacy;
- Put on disposable gloves;
- Monitor the package for removable contamination. If wipe tests indicate contamination levels greater than 22 dpm/cm^2 over a 300 cm^2 area, take the following actions:
  - Notify the customer and VDH; and
  - Survey the driver/courier who retrieved the waste and the vehicle used to transport the waste to the radiopharmacy.
  - Decontaminate the package or remove it from service for decay.
- Open the package and identify each nuclide in the shielded containers.
- Dispose of radioactive waste into the appropriate container for the half-life of the nuclide being disposed, in accordance with the radiopharmacy's procedures for disposal of waste by decay-in-storage.
- Survey the dose shields for contamination with a low-level survey meter. Any dose shield that indicates an activity exceeding background should be decontaminated or removed from service.

Appendix T:

VDH Incident Notifications

Table 13: Typical Notifications Required for Radiopharmacy Licensees

Event	Telephone Notification	Written Report	Regulatory Requirement
Theft or loss of material	Immediate	30 days	**12VAC5-481-1090**
Whole body dose greater than 0.25 Sv (25 rems)	Immediate	30 days	**12VAC5-481-1100**
Extremity dose greater than 2.5 Sv (250 rems)	Immediate	30 days	**12VAC5-481-1100**
Intake of five times the annual limit on intake	Immediate	30 days	**12VAC5-481-1100**
Removable contamination exceeding the limits of **12VAC5-481-3080** (beta/gamma/low toxicity alpha – 22 dpm/cm^2; all other alpha – 2.2 dpm/cm^2)	Immediate	30 days	**12VAC5-481-900**
External radiation levels exceeding the limits of **12VAC5-481-3080** (any point on the surface – 2 mSv/hr (200 mrem/hr))	Immediate	None	**12VAC5-481-900**
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	**12VAC5-481-1100**
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	**12VAC5-481-1100**
Intake one annual limit on intake	24 hours	30 days	**12VAC5-481-1100**
Occupational dose greater than the applicable limit in **12VAC5-481-640**	None	30 days	**12VAC5-481-1110**
Dose to individual member of public greater than 1 mSv (100 mrems)	None	30 days	**12VAC5-481-1110**
Filing petition for bankruptcy under 11 U.S.C.	None	Immediately after filing petition	**12VAC5-481-500**
Expiration of license	None	60 days	**12VAC5-481-500**
Decision to permanently cease licensed activities at **entire site**	None	60 days	**12VAC5-481-510**
Decision to permanently cease licensed activities in any **separate building or outdoor area** that is unsuitable for release for unrestricted use	None	60 days	**12VAC5-481-510**

Event	Telephone Notification	Written Report	Regulatory Requirement
No principal activities conducted for 24 months **at the entire site**	None	60 days	**12VAC5-481-510**
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	Immediate	30 days	**12VAC5-481-1100**
An unplanned contamination event involving greater than 5 times the ALI, and half-life greater than 24 hours requiring access to be restricted for more than 24 hours	24 hours	30 days	**12VAC5-481-1100**
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	**12VAC5-481-1100**
Unplanned fire or explosion that affects the integrity of any radioactive material or device, container, or equipment with radioactive material	24 hours	30 days	**12VAC5-481-1100**

Note: Telephone notifications shall be made to VDH at (804) 864-8150 (7:45 a.m. until 4:30 p.m.) and in an emergency to (800) 468-8892 or (804) 674-2400 (after hours).