

VIRGINIA DEPARTMENT OF HEALTH
DIVISION OF RADIOLOGICAL HEALTH



NRC AGREEMENT STATE APPLICATION

Commonwealth of Virginia
Radiation Protection Regulatory Guide



**Guidance for Portable Gauges or XRF
Devices**

EPI-720 A

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

EXECUTIVE SUMMARY

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

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

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

This VAREG ‘Guidance for Portable Gauge or XRF Devices’ has been developed to streamline the application process for a Portable Gauge or XRF License. A copy of the VDH Form, ‘Application for Radioactive Material License Authorizing the use of Sealed Sources in Portable Gauges or XRF Devices’, is located in **Appendix A** of this guide.

Appendix B through **L** provides examples, models and additional information that can be used when completing the application.

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

In summary, the applicant will need to do the following to submit an application for a Portable Gauge Device or XRF license:

- Use this regulatory guide to prepare the VDH Form, 'Application for Radioactive Material License Authorizing the use of Sealed Sources in Portable Gauges or XRF Devices' (**Appendix A**).
- Complete the VDH Form, 'Application for Radioactive Material License Authorizing the use of Sealed Sources in Portable Gauges or XRF Devices' (**Appendix A**). See 'Contents of Application' of the guide for additional information.
- Include any additional attachments.

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

Please identify all attachments with the applicant's name and license number (if a renewal).

- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original signed application along with attachments (if any).
- Submit the application fee (for new licensees only).
- Retain one copy of the licensee application and attachments (if any) for your future reference. You will need this information because the license will require that radioactive material be possessed and used in accordance with statements, representation, and procedures provided in the application and supporting documentation.

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

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ABBREVIATIONS

ALARA	as low as reasonably achievable
ALI	annual limit on intake
bkg	background
Bq	Becquerel
CFR	Code of Federal Regulations
Ci	Curie
cc	centimeter cubed
cm ²	centimeters squared
cpm	counts per minute
DOE	United States Department of Energy
DOT	United States Department of Transportation
dpm	disintegrations per minute
GM	Geiger-Mueller
GPO	Government Printing Office
IN	Information Notice
mCi	millicurie
mR	milliroentgen
mrem	millirem
mSv	millisievert
NIST	National Institute of Standards and Technology
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OSL	optical stimulated luminescent dosimeters
RG	Regulatory Guide
RQ	Reportable Quantities
RSO	Radiation Safety Officer
SI	International System of Units (abbreviated SI from the French Le Système Internationale d'Unites)
SS&D	Sealed Source and Devices Bulletin Board System (BBS)
SSD	Sealed Source and Device
SSDR	Sealed Source and Device Registration
Sv	Sievert
TEDE	total effective dose equivalent
TLD	thermoluminescent dosimeters
TI	Transportation Index
VDH	Virginia Department of Health
XRF	X-ray Fluorescence Analyzer
μCi	microcurie
%	percent

PURPOSE OF GUIDE

This document provides guidance to an applicant in preparing a license application for a portable gauge or XRF license. It also provides guidance on VDH's criteria for evaluating a portable gauge or XRF license application. It is not intended to address the research and development of gauging devices or the commercial aspects of manufacturing, distribution, and service of such devices. Within this document, the phrases, 'portable gauge', 'gauging devices', or 'XRF' and the term 'gauge' may be used interchangeably.

This guide addresses the variety of radiation safety issues associated with portable gauges and XRFs of many designs. Portable gauges are of many different designs based, in part, on their intended use (e.g., to measure moisture, density, thickness of asphalt, liquid level). Because of differences in design, manufacturers provide appropriate instructions and recommendations for proper operation and maintenance. In addition, with gauges and XRFs of varying designs, the sealed sources may be oriented in different locations within the devices, resulting in different radiation safety problems.

This guide describes the information needed to complete VDH Form, 'Application for Radioactive Material License Authorizing the Use of Sealed Sources in Portable Gauges or XRF Devices', (**Appendix A**).

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

- **Rule** - references the requirements of 12VAC5-481 'Virginia Radiation Protection Regulations' applicable to the item;
- **Criteria** - outlines the criteria used to judge the adequacy of the applicant's response;
- **Discussion** - provides additional information on the topic sufficient to meet the needs of most readers; and
- **Response from Applicant** – shows the appropriate item on the application and provides: response(s), offers the option of an alternative response, or indicates that no response is needed on that topic.

The information submitted in the application must be sufficient to demonstrate that proposed equipment, facilities, personnel, and procedures are adequate to protect the health and safety of the citizens of the Commonwealth of Virginia in accordance with agency guidelines.

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

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

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

This VAREG provides the latest guidance and is modeled on the Nuclear Regulatory Commission's (NRC) NUREG 1556, Volume 1. The VAREG shows the requirements in terms of the **12VAC5-481 'Virginia Radiation Protection Regulations'** and provides a user-friendly format to assist with the preparation of a 'Application for Radioactive Material License Authorizing the Use of Sealed Sources in Portable Gauges or XRF Devices' license application.

LICENSES

Applicants should study this document, related guidance, and all applicable regulations carefully before completing the VDH Form, 'Application for Radioactive Material License Authorizing the Use of Sealed Sources in Portable Gauges or XRF Devices'. 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 regulatory authority.

Table 1: Who Regulates the Activity?

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

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

MANAGEMENT RESPONSIBILITY

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

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

To ensure adequate management involvement, a management representative (i.e., chief executive officer or delegate) must sign the submitted application acknowledging management’s commitments to and responsibility for 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 public, and workers are protected from radiation hazards;
- Appointment of a qualified individual who has agreed in writing to work as the RSO.

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

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 Portable Gauge Devices or XRFs licensees:

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

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

HOW TO FILE

Applicants for a materials license should do the following:

- Be sure to use the most current guidance from VDH in preparing an application.
- Complete VDH Form, 'Application for Radioactive Material License Authorizing the Use of Sealed Sources in Portable Gauges or XRF Devices' (**Appendix A**).
- For each separate sheet, other than submitted with the application, identify and key it to the item number on the application, or the topic to which it refers.
- Submit all documents on 8 ½ x 11 – inch paper.
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original, signed application.
- Retain one copy of the license application for your future reference.

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

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

WHERE TO FILE

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

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

LICENSE FEES

The appropriate fee must accompany each application or license amendment request. Refer to **12VAC5-490** to determine the amount of the fee. VDH will not issue the new license prior to fee receipt. Once technical review has begun, no fees will be refunded. Application fees will be charged regardless of the 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 the VDH's fees or completion of **Item 10** of VDH Form, 'Application for Radioactive Material License Authorizing the Use of Sealed Sources in Portable Gauges or XRF Devices' (**Appendix A**) to: **Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, Virginia 23219 or (804) 864-8150.**

CONTENTS OF AN APPLICATION

Item 1: Type of Application

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

Response from Applicant:

APPLICATION TYPE Item 1 Type of Application (Check one box) <input type="checkbox"/> New License <input type="checkbox"/> Renewal License Number _____
--

Item 2: Applicant's Name and Mailing Address

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. Notify the agency of changes in mailing address.

Response from Applicant:

Item 2 Applicant - Name and Mailing Address
Applicant - Telephone Number (Include area code)

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, 12VAC5-481-500

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

This is to ensure the following:

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

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

Notification of Bankruptcy Proceedings

Rule: 12VAC5-481-500

Criteria: Immediately following filing of voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify VDH in writing, identify the bankruptcy court in which the petition was filed and the date of filing.

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

Item 3: Contact Person

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

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

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

Response from Applicant:

Item 3 Contact Person -- Name
Contact Person - Telephone Number (Include area code)

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

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

Criteria: Most applicants need to provide two types of information in response to **Item 4:**

- Description of storage, use, and dispatch locations
- Specification of whether they intend to use the portable gauge or XRF at temporary job sites

Discussion: Specify the street address, city, and state or other descriptive address (such as on Highway 58, 5 miles east of the intersection of Highway 58 and State Route 19, Anytown, VA, Zip) for each permanent facility used as a location of storage or use, and each facility from which the applicant will dispatch gauge and XRF users to job sites for more than one customer. If gauges or XRFs will NOT be stored at a dispatch site, so indicate. The descriptive address should be sufficient to allow a VDH inspector to find the storage location. A Post Office Box address is not acceptable.

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).

To conduct operations at temporary jobsites (i.e., locations where work is conducted for limited periods of time and from which gauge or XRF users are NOT dispatched to jobsites for other customers), specify "*temporary job sites anywhere in Virginia where VDH maintains jurisdiction*".

Note: As discussed later under 'Financial Assurance and Record Keeping for Decommissioning', licensees need to maintain permanent records on where licensed material was used or stored while the license was in force. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). For portable gauge licensees, acceptable records are sketches or written descriptions of storage or use locations specifically listed on the license. Licensees do not need to maintain this information for temporary job sites or temporary storage locations where sources have never leaked.

Response from Applicant:

LOCATION OF RADIOACTIVE MATERIAL		
Item 4 Address(es) where radioactive material(s) will be used or possessed. Attach additional pages if necessary.		
	Address (Do not use Post Office box)	Telephone Number (Include area code)
<input type="checkbox"/> Used <input type="checkbox"/> Stored <input type="checkbox"/> Used/Stored		
<input type="checkbox"/> Used <input type="checkbox"/> Stored <input type="checkbox"/> Used/Stored		
<input type="checkbox"/> Used <input type="checkbox"/> Stored <input type="checkbox"/> Used/Stored		

Are portable gauge devices and/or portable XRFs used at temporary jobsites?: Yes No

Are portable gauge devices stored at temporary jobsites?: Yes No

If yes, check the following boxes:

- We will perform and maintain documentation of radiation surveys to ensure that radiation levels are less than 2 mR in any one hour and 100 mR/yr at all temporary job site storage locations.
- We will store the device at the temporary job site in a locked room, trailer or other secure location to prevent unauthorized removal of the device.
- We will minimize exposures for occupational and non-occupational workers when selecting storage location.
- We will limit storage at a temporary job site to 180 days per calendar year.

Item 5: Radiation Safety Officer (RSO)

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

Criteria: RSOs must have adequate training and experience. The agency will accept successful completion of one of the following as evidence of adequate training and experience:

- Portable gauge manufacturer's course for users or for RSOs
- Equivalent course that meets **Appendix D** criteria

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

Response from Applicant:

RADIATION SAFETY OFFICER	
Item 5 Radiation Safety Officer (RSO) (Attach evidence of training and experience and check one box)	
Name – Radiation Safety Officer	Telephone Number (Include area code)
<input type="checkbox"/> Before obtaining radioactive material, the proposed RSO will have successfully completed one of the training courses described in the Criteria section titled 'Radiation Safety Officer' in VAREG 'Guidance for Portable Gauge Devices or XRF Devices'.	
OR	
<input type="checkbox"/> Alternative information demonstrating that the proposed RSO is qualified by training and experience is attached.	

Note:

- It is important to notify the agency, as soon as possible, of changes in the designation of the RSO.
- Alternative responses will be reviewed against the criteria listed above.

Item 6: Training for Individuals Working in or Frequenting Restricted Areas

Rule: 12VAC5-481-450, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-2260, 12VAC5-481-2270,
12VAC5-481-2280, 12VAC5-481-2310

Criteria: Authorized users must have adequate training and experience. The agency finds that successful completion of one of the following as evidence of adequate training and experience:

- Portable gauge manufacturer's course for users
- Equivalent course that meets **Appendix D** criteria

Discussion: The individuals using the gauges or XRFs are usually referred to as authorized users. Authorized users have the responsibility to ensure the surveillance, proper use, security, and routine maintenance of portable gauges or XRFs containing licensed material.

Annual radiation safety training must be provided to individuals working in or frequenting restricted areas who receive or are likely to receive 100 mrem per year (12VAC5-481-2270).

Response from Applicant:

AUTHORIZED USERS	
Item 6 Training For Individuals Working In or Frequenting Restricted Areas (check one box)	
<input type="checkbox"/> Before using radioactive material, authorized users will have successfully completed one of the training courses described in the Criteria section titled 'Training for Individuals Working In or Frequenting Restricted Areas' in VAREG 'Guidance for Portable Gauge Devices or XRF Devices'.	
NOTE: If using an in-house training program, submit copy of course content, sample course examination and course instructor qualifications.	
OR	
<input type="checkbox"/> Documentation of the training and experience for the proposed gauge user(s) is attached.	
NOTE: These individuals will be listed on the license as authorized users. An amendment request is required to add new authorized users.	

Note:

- Records of training shall be maintained.
- Alternative responses will be evaluated against the criteria listed above.

Item 7: Radioactive Material

Item 7.1: Sealed Sources and Devices

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

Criteria: Licensees will only be authorized for sealed sources and devices registered by the NRC or another Agreement State.

Discussion: NRC or another Agreement State performs a safety evaluation of gauges or XRFs before authorizing a manufacturer to distribute the gauges or XRFs to specific licensees. The safety evaluation is documented in a Sealed Source and Device Registration (SSDR) Certificate, also called an SSDR Sheet. When issuing a portable gauge or XRF license, VDH usually provides a generic authorization to allow the licensee to possess and use any sealed source/device combination that has been registered by the NRC or another Agreement State. This method of authorization allows licensees flexibility in obtaining new source/device combinations without having to amend their licenses.

Consult with the proposed supplier to ensure that sources and devices conform to the SSDR Certificates registered with NRC or another Agreement State. Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective registration certificates, without obtaining VDH's prior permission in a license amendment.

SSDR Certificates contain sections on "*Conditions of Normal Use*" and "*Limitation and Other Considerations of Use*". These sections may include limitations derived from conditions imposed by the manufacturer or distributor, by particular conditions of use that would reduce radiation safety of the device, or by circumstances unique to the sealed source or device. 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 SSDR 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 SSDR.

Response from Applicant:

RADIOACTIVE MATERIAL	
Item 7 Radioactive Material (Attach additional pages if necessary)	
Element and mass number	
Source manufacturer and model number	Maximum activity per source
Device manufacturer and model number	Intended Use

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

Item 7.2: Purpose(s) for Which Licensed Material Will Be Used

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

Criteria: Proposed activity is authorized by 12VAC5-481 'Virginia Radiation Protection Regulations' and devices will be used only for the purposes for which they were designed and according to the manufacturer's recommendations for use as specified in an approved SSDR Sheet.

Response from Applicant: Include description of intended use on **Item 7** in appropriate box.

Note:

- A VDH license does not relieve a licensee from complying with other applicable federal, state, or local regulations.
- The typical portable gauge license authorizes use "*to measure physical properties of materials*".
- Unusual uses will be evaluated on a case-by-case basis and the authorized use condition will reflect approved uses.

Item 7.3: Financial Assurance and Recordkeeping for Decommissioning

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-1161

Criteria: Portable gauge or XRF licensees possessing sealed sources containing radioactive material in excess of the limits specified in 12VAC5-481-450 C must provide evidence of financial assurance for decommissioning.

Licensees are required to maintain, in an identified location, decommissioning records related to structures and equipment where gauges or XRFs are used or stored and to leaking sources. Licensees must transfer records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with 12VAC5-481-500 B or to the agency before the license is terminated.

Discussion: The requirements for financial assurance are specific to the types and quantities of radioactive material authorized on a license. Most portable gauge applicants and licensees do not

need to comply with the financial assurance requirements because the thresholds for sealed sources are 3.7×10^6 gigabecquerels (100,000 curies) of cesium-137 or 3.7×10^3 gigabecquerels (100 curies) of americium-241 or californium-252. Thus, a licensee would need to possess hundreds of gauges (typically containing about 0.30 gigabecquerels (8 millicuries) of cesium-137 and 1.5 gigabecquerels (40 millicuries) of americium-241) before the financial assurance requirements would apply. Since the standard portable gauge license does not specify the maximum number of gauges that the licensee may possess (allowing the licensee flexibility in obtaining gauges as needed without amending its license), it contains a condition requiring the licensee to limit its possession of gauges to quantities not requiring financial assurance for decommissioning. Applicants and licensees desiring to possess gauges exceeding the threshold amounts must submit evidence of financial assurance.

The same regulation also requires that licensees maintain records important to decommissioning in an identified location. All portable gauge licensees need to maintain records of structures and equipment where gauges are used or stored at locations specifically listed on the license. As-built drawings with modifications of structures and equipment shown as appropriate fulfill this requirement. If drawings are not available, licensees may substitute appropriate records concerning the areas and locations. In addition, if portable gauge licensees have experienced unusual occurrences (e.g., leaking sources, other incidents that involve spread of contamination), they also need to maintain records about contamination that remains after cleanup or that may have spread to inaccessible areas.

For portable gauge licensees whose sources have never leaked, acceptable records important to decommissioning are sketches or written descriptions of portable gauge storage or use locations specifically listed on the license. Similar information need not be maintained for temporary job sites.

Response from Applicant: No response is needed from most applicants. If financial assurance is required submit evidence.

Reference: NRC Regulatory Guide 3.66, "*Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70 and 72*", is available from the NRC upon request.

Item 8: Facilities and Equipment

Rule: 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-840, 12VAC5-481-850, 12VAC5-481-860

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

Discussion: 12VAC5-481-450 A states that an application will be approved if, among other things, the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to the public's health and safety. 12VAC5-481-840 states that sources of radiation shall be secured against unauthorized removal from the place of storage and, when in an unrestricted area and not in storage, shall be under the constant surveillance and immediate control of the licensee or registrant. Refer to **Appendix L** for further security guidance.

The key elements for portable gauge or XRF applicants are ensuring compliance with public dose limits and maintaining adequate security and control over the gauges or XRFs. These issues are covered under 'Public Dose' and 'Operating and Emergency Procedures'.

Provide the following on the facility diagrams:

- Drawings should be to scale, and indicate the scale used;
- Location, room numbers, and principal use of each room or area where radioactive material is used or stored;
- Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below; and,
- If multiple locations of storage, indicate address on diagram.

Response from Applicant:

FACILITIES AND EQUIPMENT
Item 8 Facilities And Equipment (Check box and attach diagram.)
<input type="checkbox"/> Diagrams of radioactive material storage area(s) are attached.

Item 9: Radiation Safety Program

Item 9.1: Audit Program

Rule: 12VAC5-481-450, 12VAC5-481-500, 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 the VDH and DOT regulations, and the terms and conditions of the license;
- Occupational doses and doses to members of the public are as low as reasonably achievable (ALARA) (12VAC5-481-630); and
- Records of audits and other reviews of program content are maintained for 3 years.

Discussion: Appendix F contains a suggested audit program that is specific to the use of portable gauges or XRFs and is acceptable to the agency. All areas indicated in Appendix F may not be applicable to every licensee and may not need to be addressed during each audit.

Currently the agency's emphasis in inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of gauge users in the field to determine if, for example, operating and emergency procedures are available, 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.

Response From Applicant:

Item 9 Radiation Safety Program
Item 9.1 Audit Program
The applicant is not required to submit its audit program to the agency for review during the licensing phase. This matter will be examined during an inspection.

Item 9.2: Termination of Activities

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-1161

Criteria: The licensee must do the following:

- Notify VDH, in writing, within 60 days, when principal activities have not been conducted for a period of 24 months or a decision is made to permanently cease licensed activities.
- Certify the disposition of licensed materials by submission of VDH Form, ‘Certificate of Disposition of Radioactive Material’.
- Before a license is terminated, send the records important to decommissioning, as required by **12VAC5-481-571 D** to the agency. If licensed activities are transferred or assigned in accordance with **12VAC5-481-500 B**, transfer records important to decommissioning to the new licensee.

Discussion: For guidance on the disposition of licensed material, see the section on ‘Waste Management - Gauge Disposal or Transfer’. For guidance on decommissioning records, see the section under ‘Radioactive Materials’ on ‘Financial Assurance and Record keeping for Decommissioning’.

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

Response from Applicant:

Item 9.2 Termination Of Activities (Check box)
 We will notify VDH, in writing, within 60 days of the decision to permanently cease radioactive material use: (12VAC5-481-510)

Item 9.3: Instruments

Rule: 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-720, 12VAC5-481-750, 12VAC5-481-1000

Criteria: A radiation survey meter should:

- Be capable of detecting gamma radiation
- Be calibrated on an interval not to exceed 12 months and after each instrument servicing.
- Be checked for functionality before use (e.g., with the gauge or a check source)

Discussion: Each year there are a number of incidents involving gauges at construction sites (e.g., construction equipment running over the gauge). It is important to determine as soon as possible after an incident, by the use of a radiation survey meter, whether the shielding and source are intact.

Portable gauges licensees are required by 12VAC5-481-450 A to have equipment, facilities, and procedures which are adequate to minimize danger to public health and safety. VDH requires that a calibrated radiation survey instrument be available when portable gauge is used. XRF licensees are not required to have a radiation survey instrument for use.

Response from Applicant:

Item 9.3 Instruments (Check one box)	
<input type="checkbox"/> We will possess and use a radiation survey meter that meets the Criteria in the section titled 'Instruments' in VAREG 'Guidance for Portable Gauges or XRF Devices'.	OR
<input type="checkbox"/> We will submit an alternative procedure for determining source integrity after an incident involving the portable gauge(s). (Procedures are attached)	OR
<input type="checkbox"/> Not Applicable (XRF Device(s))	

Note: Prior to non-routine maintenance that requires removing the source or source rod from the gauge a calibrated and operable radiation survey instrument will be required.

Item 9.4: Material Receipt and Accountability

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-900, 12VAC5-481-980, 12VAC5-481-1090, 12VAC5-481-3091, 12VAC5-481-3100

Criteria: Licensees must do the following:

- Maintain records of receipt, transfer, and disposal of gauges or XRFs 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: Licensed materials must be tracked from ‘cradle to grave’ in order to ensure gauge accountability, identify when gauges or XRFs could be lost, stolen, or misplaced, and ensure that, if the licensee possesses gauges exceeding threshold amounts, the licensee complies with financial assurance requirements in **12VAC5-481-450 C**.

‘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).

Response from Applicant:

<p>Item 9.4 Material Receipt And Accountability (Check one box)</p> <p><input type="checkbox"/> We will conduct physical inventories, at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will submit a description of the frequency and procedures for ensuring that no gauge has been lost, stolen or misplaced. (Procedures are attached)</p>

Item 9.5: Occupational Dosimetry

Rule: 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-700, 12VAC5-481-710, 12VAC5-481-750, 12VAC5-481-760, 12VAC5-481-770, 12VAC5-481-1040, 12VAC5-481-1130, 12VAC5-481-1140, 12VAC5-481-2280

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 2**.

Discussion: Under conditions of routine use, a personnel monitoring device (dosimetry) is not required. However a written evaluation demonstrating that users are not likely to exceed 10 percent of the applicable limits as shown in **Table 2** is required. **Appendix I Part 1** provides guidance on preparing this written evaluation.

Licensees should reevaluate need for dosimetry upon significant program changes.

Licensees providing dosimetry should use either film badges or optically stimulated luminescent (OSLs) that are supplied by an NVLAP-approved processor. The exchange frequency for film badges is usually monthly due to technical concerns about film fading. Applicants should verify that the processor is NVLAP-approved. Consult the NVLAP-approved processor for its recommendations for exchange frequency and proper use.

Licensees requesting authorization for non-routine maintenance must provide users dosimetry.

Table 2: Occupational Dose Limits For Adults

Occupational Dose Limits for Adults (12VAC5-481-640)	
<u>Body Location</u>	<u>Dose (Annual)</u>
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	

Response from Applicant:

<p>Item 9.5 Occupational Dosimetry (Check one box)</p> <p><input type="checkbox"/> We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged at a frequency recommended by the processor.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will maintain, for inspection by VDH, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in 12VAC5-481-640. (See Appendix I in VAREG 'Guidance for Portable Gauges or XRF Devices'.)</p>

Reference: National Institute of Standards and Technology (NIST) Publication 810, "*National Voluntary Laboratory Accreditation Program Directory*", is published annually and is available for purchase from United States Government Printing Office and on the Internet at the following address:
<http://ts.nist.gov/ts/htdocs/210/214/dosim.htm>.

Item 9.6: Public Dose

Rule: 12VAC5-481-630, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-840, 12VAC5-481-1050, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-3070

Criteria: Licensees must do the following:

- Ensure that licensed gauges will be used, transported, and stored in such a way that members of the public will not receive more than 1 millisievert (100 millirem) in one year, and the dose in any unrestricted area will not exceed 0.02 millisievert (2 millirem) in any one hour, from licensed operations.
- Control and maintain constant surveillance over gauges that are not in storage and secure stored gauges from unauthorized removal or use. Gauges should be stored away from occupied areas.

Discussion: Members of the public include persons who live, work, or may be near locations where portable gauges or XRFs are used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where gauges or XRFs are used or stored.

Public dose is also affected by the choice of storage location and conditions. Since a gauge or XRF presents a radiation field during storage, it must be stored so that the radiation level in an unrestricted area (e.g., an office or the exterior surface of an outside wall) does not exceed 1 mSv (100 mrem) in a year or 0.02 mSv (2 mrem) in any one hour. Use the concepts of time, distance, and shielding when choosing a permanent or temporary storage location. Decreasing the time spent near a gauge or XRF, increasing the distance from the gauge or XRF, and using shielding (i.e., brick, concrete, lead, or other solid walls) will reduce the radiation exposure. As a rule of thumb, gauges and XRFs should be stored as far away as possible from areas that are occupied by members of the public.

Licenses can determine the radiation levels adjacent to the storage location either by calculations or a combination of direct measurements and calculations using some or all of the following: typical known radiation levels provided by the manufacturer, the 'inverse square' law to evaluate the effect of distance on radiation levels, and occupancy factors to account for the actual presence of the member of the public and of the gauge(s) or XRF(s). See **Part 2 of Appendix I** for examples.

If, after making an initial evaluation, a licensee makes changes affecting the storage area (e.g., changing the location of gauges or XRFs within the storage area, removing shielding, adding gauges or XRFs, changing the occupancy of adjacent areas, moving the storage area to a new location), then the licensee must ensure that gauges and XRFs are properly secured, perform a new evaluation to ensure that the public dose limits are not exceeded, and take corrective action, as needed.

Response from Applicant:

Item 9.6 Public Dose

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

Item 9.7: Operating and Emergency Procedures

Rule: 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-630, 12VAC5-481-750, 12VAC5-481-840, 12VAC5-481-860, 12VAC5-481-880, 12VAC5-481-900, 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1150, 12VAC5-481-2260, 12VAC5-481-3091

Criteria: Each applicant must develop, implement, and maintain operating and emergency procedures containing the following elements:

- Instructions for using the portable gauge or XRF and performing routine maintenance, according to the manufacturer's recommendations and instructions
- Instructions for maintaining security during storage and transportation
- Instructions to keep the gauge or XRF under control and immediate surveillance during use
- Steps to take to keep radiation exposures ALARA
- Steps to maintain accountability during use

- Steps to control access to a damaged gauge or XRF and
- Steps to take, and whom to contact, when a gauge or XRF has been damaged.

If gauges are used for measurements with the unshielded source extended more than 3 feet beneath the surface, licensees must do the following:

- require use of surface casing or alternative procedures to ensure the source can move freely in the hole
- provide instructions for procedures to follow to retrieve a stuck source
- require reporting to the agency, pursuant to **12VAC5-481-1110**, when a stuck source cannot be retrieved.

Provide copies of operating and emergency procedures to all gauge or XRF users and at each job site.

Discussion: Lost or stolen gauges or XRFs and gauges damaged by heavy equipment during use at job sites are the most common occurrences that present a potentially significant radiation safety risk. Operating and emergency procedures shall be developed to minimize these risks. The agency considers security of gauges and XRFs extremely important and lack of security is a significant violation.

Certain portable gauges are used to make measurements with the unshielded source extended more than 3 feet beneath the surface. Unless precautionary measures are taken, it is possible for the source to be buried under dirt or concrete that collapses around the source during the measurements. Precautionary measures need to be planned in advance to prevent these sources from being buried and to recover sources should they become stuck. To ensure that the hole is free of debris, it is acceptable for licensees to use surface casing from the lowest depth to 12 inches above the surface. It is not likely that debris will re-enter the cased hole and the source will be able to move freely. If it is not feasible to extend the casing 12 inches above the surface, licensees may cap the hole and use dummy probes before making measurements with an unshielded source to ensure that the hole is free of obstructions.

To avoid lost or stolen gauges, licensees must keep the gauges under constant surveillance (when in use or idle) or secured against unauthorized use or removal through leaving in secured position in a locked area (i.e.; trailer, shed, etc). Notify VDH when gauges or XRFs are lost, stolen, or certain other conditions are met.

See **Appendix H** for sample operating and emergency procedures and **Appendix L** for security guidance.

Response from Applicant:

<p>Item 9.7 Operating and Emergency Procedures (Check one box)</p> <p><input type="checkbox"/> We will implement and maintain the operating and emergency procedures in Appendix H of VAREG 'Guidance for Portable Gauges or XRF Devices' and provide copies of these procedures to all gauge or XRF users and at each job site.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> Operating and emergency procedures will be developed, implemented, maintained and provided to all gauge or XRF users at each job site and will meet criteria in the section titled 'Operating and Emergency Procedures' in VAREG 'Guidance for Portable Gauges or XRF Devices'. (Procedures are attached)</p>

Note: Telephone notifications shall be made to the agency at (804) 864-8150 during normal business hours (8 a.m. – 4:30 p.m.) For immediate notifications after normal business hours, the 24 hour emergency telephone number is (804) 674-2400 or (800) 468-8892. Identify the emergency as radiological.

Item 9.8: Leak Tests

Rule: 12VAC5-481-180, 12VAC5-481-740, 12VAC5-481-1010, 12VAC5-481-1150

Criteria: VDH requires testing to determine whether there is any radioactive leakage from the source in the device. 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: 12VAC5-481-740 requires performance of leak tests at intervals approved by the NRC or another Agreement State and specified in the SSDR Sheet. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample must be capable of detecting 185 becquerels (0.005 microcurie) of radioactivity. **Appendix J** discusses leak testing and contains samples of performing leak tests.

Manufacturers, consultants, and other organizations may be authorized by VDH, the NRC or another Agreement State to either perform the entire leak test sequence for other licensees or provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample according to the gauge or XRF manufacturer's and the kit supplier's instructions and return it to the kit supplier for evaluation and reporting results. Licensees may also be authorized to conduct the entire leak test sequence themselves.

Response from Applicant:

Item 9.8 Leak Tests (Check one box)	
<input type="checkbox"/>	Leak tests will be performed by an organization authorized by VDH, the NRC or another Agreement State to provide leak testing services to other licensees; or by using a leak test kit supplied by an organization licensed by VDH, the NRC or another Agreement State to provide leak test kits to other licensees according to kit supplier's instructions.
List Name and License number of organization authorized to perform or analyze leak tests (Specify whether VDH, NRC, or another Agreement State)	
Organization Name _____	License Number _____
	Issuing Agency _____
NOTE: An alternate organization may be used to perform or analyze leak tests without amending the license, provided the organization is specifically authorized by VDH, the NRC, or another Agreement State.	
OR	
<input type="checkbox"/>	We will perform leak testing and sample analysis and will follow the model procedures in Appendix J of VAREG 'Guidance for Portable Gauges or XRF Devices'.
OR	
<input type="checkbox"/>	We will submit alternative procedures. (Procedures are attached)

Note: Requests for authorization to perform leak testing and sample analysis will be reviewed on a case-by-case basis and, if approved, VDH will authorize via a license condition.

Item 9.9: Maintenance

Rule: 12VAC5-481-450, 12VAC5-481-490 B, 12VAC5-481-500, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-980

Criteria: Licensees must routinely clean and maintain gauges and XRFs according to the manufacturer's recommendations and instructions. For gauges with a source rod, radiation safety procedures for routine cleaning and lubrication of the source rod and shutter mechanism (e.g., to remove caked dirt, mud, asphalt, or residues from the source rod; lubricate the shutter mechanism) must consider ALARA and ensure that the gauge functions as designed and source integrity is not compromised.

Non-routine maintenance or repair (beyond routine cleaning and lubrication) that involves detaching the source or source rod from the device and any other activities during which personnel could receive radiation doses exceeding VDH limits must be performed by the gauge manufacturer or a person specifically authorized by VDH, the NRC or another Agreement State. **XRF users are not allowed to perform non-routine maintenance, the XRF manufacturer must perform all non-routine maintenance.** Requests for specific authorization to perform non-routine maintenance or repair (see **Appendix G**) must demonstrate that personnel performing the work:

- Have adequate training and experience;
- Use equipment and procedures that ensure compliance with regulatory requirements, and consider ALARA; and
- Ensure that the gauge functions as designed and that source integrity is not compromised.

Discussion: VDH permits portable gauge licensees to perform routine maintenance of the gauges provided that they follow the gauge manufacturer's recommendations and instructions. Although manufacturers may use different terms, 'routine maintenance' includes, but is not limited to: cleaning, lubrication, changing batteries or fuses, repairing or replacing a handle. Routine maintenance does NOT include any activities that require removing the sealed source or source rod from the gauge.

The licensee will state that any cleaning, maintenance, or repair of gauges that requires detaching the source or source rod from the gauge shall be performed only by the manufacturer or other persons specifically licensed by VDH, the NRC or another Agreement State to perform such services. Most licensees do not perform non-routine maintenance or repair operations that require detaching the source or source rod from the gauge; they usually return the gauge to the manufacturer. Applicants seeking authorization to detach the source or source rod from the device must submit specific procedures for review. See **Appendix G** for more information.

Response from Applicant:

Item 9.9 Maintenance (Check one box for routine cleaning and lubrication and one for non-routine maintenance)

Routine cleaning and lubrication:

- We will implement and maintain procedures for routine maintenance of our gauge(s) or XRF(s) according to each manufacturer's recommendations and instructions.

OR

- Alternative procedures are attached.

Non-routine maintenance:

- We will send the gauge(s) or XRF(s) to the manufacturer or other person authorized by VDH, the NRC or another Agreement State to perform non-routine maintenance or repair operations that require the removal of the source or source rod from the gauge(s) or XRF(s).

OR

- We will provide the information listed in Appendix G of VAREG 'Guidance for Portable Gauges or XRF Devices' to support a request to perform this work 'in house'. (Procedures are attached)

Item 9.10: Transportation

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

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

Discussion: DOT requirements are often overlooked by portable gauge licensees. During an inspection the agency inspects and enforces DOT's regulations governing the transport of radioactive materials. **Appendix K** lists major DOT regulations and provides a sample shipping paper for portable gauges. See **Appendix L** for information on security requirements.

XRF users typically are not required to have shipping papers; however, a certification statement (49 CFR 173.422 (a)(2)), and the name of the consignor or consignee, must be included with the XRF device whenever it is transported or shipped. See 49 CFR 173.424 for DOT requirements concerning Excepted packages for radioactive instruments and articles. See **Appendix B** for Sample XRF Certification Statement.

Response from Applicant:

Item 9.10 Transportation

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

Item 9.11: Waste Management - Gauge or XRF Disposal and Transfer

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-910, 12VAC5-481-980, 12VAC5-481-2980, 12VAC5-481-3100

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

Discussion: When disposing of portable gauges or XRFs, licensees must transfer them to an authorized recipient. Authorized recipients are the original manufacturer of the device, a commercial firm licensed by VDH, the NRC or another Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material (i.e., their license specifically authorizes the radionuclide and the use).

Before transferring radioactive material, a licensee must verify that the recipient is properly authorized to receive it using one of the methods described in **12VAC5-481-570 D**. In addition, all packages containing radioactive sources must be prepared and shipped in accordance with VDH and DOT regulations. Records of the transfer must be maintained as required by **12VAC5-481-100** and **12VAC5-481-571**.

Response from Applicant:

Item 9.11 Waste Management - Gauge or XRF Disposal And Transfer (Check box)	
<input type="checkbox"/>	We will transfer the gauge or XRF to the manufacturer for disposal or transfer the device to a specific licensee, authorized to receive radioactive material.

Note: Because of the difficulties and costs associated with disposal of americium-241 sealed neutron sources, applicants should preplan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement.

Item 10: Specific License Fee

On VDH Form, 'Application for Radioactive Material License Authorizing the Use of Sealed Sources in Portable Gauges or XRF Devices' enter the fee category and the amount. Refer to **12VAC5-490** for fee category and application fees. Enclose fee with the application.

Response from Applicant:

SPECIFIC LICENSE FEE	
Item 10 License Fees (Refer to 12VAC5-490.)	
Category: _____	Licensed fee enclosed: <input type="checkbox"/> Yes <input type="checkbox"/> No Amount Enclosed \$

Item 11: Certification

Criteria:

- Individuals acting in a private capacity are required to sign and date VDH Form, 'Application for Radioactive Material License Authorizing the Use of Sealed Sources in Portable Gauges or XRF Devices' (**Appendix A**).
- Senior representatives of the corporation or legal entity filing the application should sign and date VDH Form, 'Application for Radioactive Material License Authorizing the Use of Sealed Sources in Portable Gauges or XRF Devices' (**Appendix A**).

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

Response from Applicant:

Item 11	
I hereby certify that this application was prepared in conformance with 12VAC5-481 'Virginia Radiation Protection Regulations' and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.	
SIGNATURE - Applicant Or Authorized Individual	Date signed
Print Name and Title of above signatory	

Note:

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

Appendix A

VDH Form

‘Application For Radioactive Material License

Authorizing the Use of Sealed Sources in Portable Gauge Devices and XRF Devices’



APPLICATION FOR RADIOACTIVE MATERIAL LICENSE AUTHORIZING THE USE OF SEALED SOURCES IN PORTABLE GAUGES OR XRF DEVICES

The Virginia Department of Health (VDH) is requesting disclosure of information. Completion of this form is required to obtain a Radioactive Material License. Failure to provide all requested information may result in denial or delay of a Radioactive Material License.

Instructions – Complete all items. Refer to VAREG ‘Guidance for Portable Gauges or XRF Devices’ for additional information. Use supplementary sheets if necessary. Retain a copy and submit the original of the entire application to: Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219.

APPLICATION TYPE

Item 1 Type of Application (Check one box)

- New License Renewal License Number _____

CONTACT INFORMATION

Item 2 Applicant - Name and Mailing Address

Item 3 Contact Person – Name

Applicant - Telephone Number (Include area code)

Contact Person - Telephone Number
(Include area code)

LOCATION OF RADIOACTIVE MATERIAL

Item 4 List all address(es) where radioactive material(s) will be used or possessed. Attach additional pages if necessary.

	Address (Do not use Post Office box)	Telephone Number (Include area code)
<input type="checkbox"/> Used <input type="checkbox"/> Stored <input type="checkbox"/> Used/Stored		
<input type="checkbox"/> Used <input type="checkbox"/> Stored <input type="checkbox"/> Used/Stored		
<input type="checkbox"/> Used <input type="checkbox"/> Stored <input type="checkbox"/> Used/Stored		

Are portable gauge devices and/or portable XRFs used at temporary jobsites?: Yes No

Are portable gauge devices stored at temporary jobsites?: Yes No

If yes, check the following boxes:

- We will perform and maintain documentation of radiation surveys to ensure that dose levels are less than 2 mrem in any one hour and 100 mrem/yr at all temporary job site storage locations.
- We will store the device at the temporary job site in a locked room, trailer or other secure location to prevent unauthorized removal of the device.
- We will minimize exposures for occupational and non-occupational workers when selecting storage location.
- We will limit storage at a temporary job site to 180 days per calendar year.

RADIATION SAFETY OFFICER

Item 5 Radiation Safety Officer (RSO) (Attach evidence of training and experience and check one box)

Name – Radiation Safety Officer	Telephone Number (Include area code)
---------------------------------	--------------------------------------

- Before obtaining radioactive material, the proposed RSO will have successfully completed one of the training courses described in the Criteria section titled “Individual(s) Responsible for Radiation Safety Program and Their Training and Experience-Radiation Safety Officer” in VAREG ‘Guidance for Portable Gauges or XRF Devices’.

Or

- Alternative information demonstrating that the proposed RSO is qualified by training and experience is attached.

AUTHORIZED USERS

Item 6 Training for individuals working in or frequenting restricted areas (check one box)

- Before using radioactive material, authorized users will have successfully completed one of the training courses described in the Criteria section titled “Training for Individuals Working In or Frequenting Restricted Areas” in VAREG ‘Guidance for Portable Gauges or XRF Devices.’

NOTE: If using an in-house training program, submit copy of course content, sample course examination and course instructor qualifications.

Or

- Documentation of the training and experience for the proposed gauge user(s) is attached.

NOTE: These individuals will be listed on the license as authorized users. An amendment request is required to add new authorized users.

RADIOACTIVE MATERIAL

Item 7 Radioactive Material (Attach additional pages if necessary)

Element and mass number	
Source manufacturer and model number	Maximum activity per source
Device manufacturer and model number	Intended Use

FACILITIES AND EQUIPMENT

Item 8 Facilities And Equipment (Check box and attach diagram.)

- Diagrams of radioactive material storage area(s) are attached.

RADIATION SAFETY PROGRAM

Item 9 Radiation Safety Program

Item 9.1 Audit Program

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

Item 9.2 Termination Of Activities (Check box)

- We will notify VDH, in writing, within 60 days of the decision to permanently cease radioactive material use. (12VAC5-481-500)

Item 9.3 Instruments (Check one box)

- We will possess and use a radiation survey meter that meets the Criteria in the section titled "Instruments" in VAREG 'Guidance for Portable Gauges or XRF Devices.'

Or

- We will submit an alternative procedure for determining source integrity after an incident involving the portable gauge(s). (Procedures are attached)

Or

- Not Applicable [XRF Device(s)]

Item 9.4 Material Receipt And Accountability (Check one box)

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

Or

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

Item 9.5 Occupational Dosimetry (Check one box)

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

Or

- We will maintain, for inspection by VDH, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in 12VAC5-481-640. (See Appendix I in VAREG 'Guidance for Portable Gauges or XRF Devices.')

Item 9.6 Public Dose

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

Item 9.7 Operating And Emergency Procedures (Check one box)

- We will implement and maintain the operating and emergency procedures in Appendix H of VAREG 'Guidance for Portable Gauges or XRF Devices' and provide copies of these procedures to all gauge or XRF users and at each job site.

Or

- Operating and emergency procedures will be developed, implemented, maintained and provided to all gauge or XRF users at each job site and will meet criteria in the section titled "Radiation Safety Program – Operating and Emergency Procedures" in VAREG 'Guidance for Portable Gauges or XRF Devices.' (Procedures are attached)
-

Item 9.8 Leak Tests (Check one box)

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

List Name and License number of organization authorized to perform or analyze leak tests. (Specify whether VDH, NRC, or another Agreement State)

Organization Name _____

License Number _____

Issuing Agency _____

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

Or

- We will perform leak testing and sample analysis and will follow the model procedures in Appendix J of VAREG 'Guidance for Portable Gauges or XRF Devices.'

Or

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

Item 9.9 Maintenance (Check one box for routine cleaning and lubrication and one for non-routine maintenance)

Routine cleaning and lubrication:

- We will implement and maintain procedures for routine maintenance of our gauge(s) or XRF(s) according to each manufacturer's recommendations and instructions.

Or

- Alternative procedures are attached:

Non-routine maintenance:

- We will send the gauge(s) or XRF(s) to the manufacturer or other person authorized by VDH, the NRC or another Agreement State to perform non-routine maintenance or repair operations that require the removal of the source or source rod from the gauge(s) or XRF(s).

Or

- We will provide the information listed in Appendix G of VAREG 'Guidance for Portable Gauges or XRF Devices' to support a request to perform this work "in house."

Item 9.10 Transportation

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

Item 9.11 Waste Management - Gauge or XRF Disposal And Transfer (Check box)

- We will transfer the gauge or XRF to the manufacturer for disposal or transfer the device to a specific licensee, authorized to receive radioactive material.

SPECIFIC LICENSE FEE

Item 10 License Fees (Refer to 12VAC5-490.)

Category: Application Fee Enclosed (For new applications):
 Yes No Amount Enclosed \$ _____

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

Item 11

I hereby certify that this application was prepared in conformance with 12VAC5-481 "Virginia Radiation Protection Regulations" and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.

SIGNATURE - Applicant Or Authorized Individual

Date signed

Print Name and Title of above signatory

Appendix B

Sample XRF Certification Statement

**“THIS PACKAGE CONFORMS TO
THE CONDITIONS AND
LIMITATIONS SPECIFIED IN 49 CFR
173.424 FOR RADIOACTIVE
MATERIAL, EXCEPTED PACKAGE-
INSTRUMENTS OR ARTICLES,
UN2910”**

Appendix C

Information Needed for Transfer of Control Application

Information Needed for Transfer of Control Application

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

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

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

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

1. Provide a complete description of the transaction (transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact who VDH may contact if more information is needed.
2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.
3. Describe any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.
4. Describe the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.
5. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to VDH, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.
6. Confirm that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

References: The information above is derived from Information Notice 89-25, Revision 1, "*Unauthorized Transfer of Ownership or Control of Licensed Activities*," which is available at the NRC's webpage at <http://www.nrc.gov>.

Appendix D

Criteria for Acceptable Training Courses for Portable Gauge Users

Criteria for Acceptable Training Courses for Portable Gauge Users

Course Content

The following are areas in which VDH considers it important that an individual have expertise for the competent operation of portable gauges and XRF devices using sealed sources of radioactive material. The course shall be at least 8 hours in length.

- I. **PRINCIPLES AND FUNDAMENTALS OF RADIATION SAFETY**
 - A. Types and Characteristics of Radiation
 1. Alpha, Beta, Gamma, X-ray and Neutron Radiation
 2. Exposure: Natural versus Man-made Radiation
 3. Irradiation versus Contamination/Internal vs. External
 4. Radioactive Material Used in Portable Gauges and XRF Devices
 - B. Units of Radiation Dose and Quantities of Radioactivity
 1. Curie, Rad, Rem and Roentgen
 2. Prefixes
 3. SI Units
 - C. Basic Math and Calculations Related to Radioactivity
 1. Radioactive Decay
 2. Dose Rates from the sources commonly used
 3. Inverse Square Law
 - D. Biological Effects of Radiation
 1. Acute, Chronic, and Genetic Effects of Exposure
 2. Radiation Protection Standards
 3. The ALARA Philosophy
 - E. Radiation levels from Radioactive Sealed Sources
 1. Survey Meter Use for Portable Gauge Users, not including XRF devices
 - F. Methods of Controlling Radiation Dose
 1. Time
 2. Distance
 3. Shielding
- II. **STATE AND FEDERAL REGULATIONS**
 - A. **12VAC5-481 'Virginia Radiation Protection Regulations'**
 - B. Title 10, Code of Federal Regulations, US Nuclear Regulatory Commission
 - C. Title 49, Code of Federal Regulations, US Department of Transportation

III. LICENSING AND INSPECTION

- A. License Items and Conditions
- B. Notices, Instructions and Reports to Workers
- C. Inspection by the Agency

IV. OPERATING AND EMERGENCY PROCEDURES

- A. Operating Procedures
 - 1. Training and Supervision
 - 2. Personnel Monitoring
 - 3. Availability of Procedures
 - 4. Security of the Gauges or Devices When Stored and At The Work Location
 - 5. ALARA Philosophy
 - 6. Transportation of the Gauges or Devices and Security
 - 7. General Rules of Use
 - 8. Posting Requirements
 - 9. Routine Maintenance
 - 10. Radiation Surveys Using Survey Meters at the Work Site for Portable Gauges
- B. Emergency Procedures
 - 1. Preventive Measures
 - 2. Emergency Response
 - 3. Notification Requirements
 - 4. Case Histories

V. TRANSFER/ DISPOSAL REQUIREMENTS

- A. State and NRC Regulations
- B. Transportation Requirements

VI. PRACTICAL TRAINING

- A. Transport/ Storage Containers
- B. Hands-on Training Specific to the Gauge or Device
 - 1. Proper Use
 - 2. Safe Handling
 - 3. Calibration of XRF Device Including Substrate Corrections
 - 4. Demonstration of Measurements of Various Materials
 - 5. Use of Survey Meters by Portable Gauge Users.

VII. Q&A SESSION

Course Examination

- 25-50 question, closed-book written test -- 70 percent grade
 - Emphasis on radiation safety of portable gauge storage, use, sealed source location, maintenance, and transportation, rather than the theory and art of making portable gauge measurements
 - Review of correct answers to missed questions with prospective gauge user immediately following the scoring of the test

Course Instructor Qualifications

Instructor should have either:

- Bachelor's degree in a physical or life science or engineering
- Successful completion of a portable gauge user course
- Successful completion of an 8 hour radiation safety course AND
- 8 hours hands-on experience with portable gauges

OR

- Successful completion of portable gauge user course
- Successful completion of 40 hour radiation safety course; AND
- 30 hours of hands-on experience with portable gauges.

Note: Licensees should maintain records of training.

Appendix E

Typical Duties and Responsibilities of the Radiation Safety Officer

Typical Duties and Responsibilities of the Radiation Safety Officer

The RSO's duties and responsibilities typically include ensuring the following:

- Stopping licensed activities that the RSO considers unsafe
- Possession, use, storage, and maintenance of sources and gauges or XRFs are consistent with the limitations in the license, the Sealed Source and Device Registration sheet(s), and manufacturer's recommendations and instructions
- Individuals using gauges are properly trained
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals; records of the results of such monitoring are maintained
- Gauges or XRFs are properly secured
- Proper authorities are notified in case of accident, damage to gauges, fire, or theft
- Unusual occurrences involving the gauge (e.g., accident, damage) are investigated, cause(s) and appropriate corrective action are identified, and corrective action is taken
- Audits are performed at least annually and documented, and corrective actions taken
- Licensed material is transported in accordance with all applicable DOT requirements
- Licensed material is disposed of properly
- Appropriate records are maintained
- Up-to-date license is maintained and amendment and renewal requests submitted in a timely manner
- Ensure two independent physical barriers are used for portable gauges not under constant supervision.

Appendix F

Portable Gauge or XRF Audit Checklist

Portable Gauge or XRF Audit Checklist

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

Licensee's name: _____ License No. _____
Auditor: _____ Date of Audit _____ Telephone No. _____

(Signature)

1. AUDIT HISTORY

- a. Last audit of this location conducted on (date) _____
- b. Were previous audits conducted yearly? (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).

2. ORGANIZATION AND SCOPE OF PROGRAM

- a. If the mailing address or places of use changed, was the license amended?
- b. If ownership changed or bankruptcy filed, was VDH prior consent obtained or was the VDH notified?
- c. If the RSO was changed, was license amended? Does new RSO meet VDH training requirements?
- d. If the designated contact person changed, was agency notified?
- e. Does the license authorize all of the radionuclides contained in gauges possessed?
- f. Are the gauges or XRFs as described in the Sealed Source and Device Registration (SSDR) Certificate or Sheet? Have copies of (or access to) SSDR Certificates? Have manufacturers' manuals for operation and maintenance?
- g. Are the actual uses of gauges consistent with the authorized uses listed on the license?
- h. Is RSO fulfilling his/her duties?

3. TRAINING AND INSTRUCTIONS TO WORKERS

- a. Were all workers who are likely to exceed 100 mrem/yr instructed per 12VAC5-481-2270? Refresher training provided, as needed (12VAC5-481-2270)?
- b. Did each gauge or XRF operator attend an approved course prior to using gauges?
- c. Are training records maintained for each gauge or XRF operator?
- d. Did interviews with operators reveal that they know the emergency procedures?
- e. Did this audit include observations of operators using the gauge or XRF in a field situation?
- f. Operating gauge or XRF? Performing routine cleaning and lubrication? Transporting gauge or XRF? Storing gauge or XRF?

- g. Did the operator demonstrate safe handling and security during transportation, use and storage?
- h. HAZMAT training provided as required? [49 CFR 172.700; 172.701; 172.702; 172.703; 172.704]

4. RADIATION SURVEY INSTRUMENTS (For Portable Gauges Users Only)

- a. If the licensee possesses its own survey meter, does it meet VDH's criteria?
- b. If the licensee does not possess a survey meter, are specific plans made to have one available?
- c. Is the survey meter needed for non-routine maintenance calibrated as required (12VAC5-481-750)?
- d. Are calibration records maintained (12VAC5-481-1000)?

5. GAUGE AND XRF INVENTORY

- a. Is a record kept showing the receipt of each gauge or XRF? (12VAC5-481-100, 12VAC5-481-571)
- b. Are all gauges or XRFs received physically inventoried every six month?
- c. Are records of inventory results with appropriate information maintained?

6. PERSONNEL RADIATION PROTECTION

- a. Are ALARA considerations incorporated into the radiation protection program? (12VAC5-481-630)
- b. Is documentation kept showing that unmonitored users receive <10% of limit?
- c. Did unmonitored users' activities change during the year which could put them over 10% of limit?
- d. If yes to c. above, was a new evaluation performed?
- e. Is external dosimetry required? (Portable gauges users are required to have and XRF users receiving >10% of limit are required to have) Is dosimetry provided to users?
 - 1) Is the dosimetry supplier NVLAP approved? (12VAC5-481-750)
 - 2) Are the dosimeters exchanged monthly for film badges and at industry recommended frequencies?
 - 3) Are dosimetry reports reviewed by the RSO when they are received?
 - 4) Are the records VDH Forms or equivalent? (12VAC5-481-1040)
 - VDH Form, 'Cumulative Occupational Exposure History' completed?
 - VDH Form, 'Occupational Exposure Record for a Monitoring Period' completed?
 - 5) If a worker declared her pregnancy, did licensee comply with 12VAC5-481-710?
 - Were records kept of embryo/fetus dose per 12VAC5-481-1040?
- f. Are records of exposures, surveys, monitoring, and evaluations maintained? (12VAC5-481-990, 12VAC5-481-1000, 12VAC5-481-1040, 12VAC5-481-1080)

g. Are annual exposure reports given to employees who receive greater than 100 mrem per year?

(12VAC5-481-2280)

7. PUBLIC DOSE

- a. Are gauges or XRFs stored in a manner to keep doses below 100 mrem in a year?
(12VAC5-481-720, 12VAC5-481-730)
- b. Has a survey or evaluation been performed per 12VAC5-481-730? Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?
- c. Do unrestricted area radiation levels exceed 2 mrem in any one hour? (12VAC5-481-720)
- d. Are gauges or XRFs being stored in a manner that would prevent unauthorized use or removal?
(12VAC5-481-840)
- e. Records maintained? (12VAC5-481-1050)

8. OPERATING AND EMERGENCY PROCEDURES

- a. Have operating and emergency procedures been developed?
- b. Do they contain the required elements?
- c. Does each operator have a current copy (with current telephone numbers) of the operating and emergency procedures?

9. LEAK TESTS

- a. Was each sealed source leak tested every 6 months or at other prescribed intervals?
- b. Was the leak test performed as described in correspondence with the agency and according to the license?
- c. Are records of results retained with the appropriate information included?
- d. Were any sources found leaking and if yes, was VDH notified?

10. MAINTENANCE OF GAUGES

- a. Are manufacturer's procedures followed for routine cleaning and lubrication of gauge and XRF?
- b. Does the source or source rod remain attached to the portable gauge during cleaning?
- c. Is non-routine maintenance performed where the source or source rod is detached from the gauge? If yes, was it performed according to license requirements (e.g., extent of work, individuals performing the work, procedures, dosimetry, survey instrument, compliance with 12VAC5-481-640 limits)? (Applies only to Portable Gauge Users, XRF users are not allowed to perform non-routine maintenance.)

11. TRANSPORTATION

Portable Gauges

- a. DOT-7A or other authorized packages used? **(49 CFR 173.415, 49 CFR 173.416(b))**
- b. Package performance test records on file?
- c. Special form sources documentation? **(49 CFR 173.476(a))**
- d. Package has 2 labels (ex. Yellow-II) with TI, Nuclide, Activity, and Hazard Class? **(49 CFR 172.403, 49 CFR 173.441)**
- e. Package properly marked? **(49 CFR 172.301, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324)**
- f. Package closed and sealed during transport? **(49 CFR 173.475(f))**
- g. Shipping papers prepared and used? **(49 CFR 172.200(a))**
- h. Shipping papers contain proper entries? {Shipping name, Hazard Class, Identification Number (UN Number), Total Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, Cargo Aircraft Only (if applicable)} **(49 CFR 172.200; 172.201; 172.202; 172.203; 172.204; 172.604)**
- i. Shipping papers within drivers reach and readily accessible during transport? **(49 CFR 177.817(e))**
- j. Secured against movement? **(49 CFR 177.834)**

XRF

- a. If shipping papers are not required, is there a certification statement **(49 CFR 173.422(a)(2))** along with the name of the consignor or consignee included with (on the package or inside the package) the XFR when transported?

12. AUDITOR'S INDEPENDENT SURVEY MEASUREMENTS (IF MADE)

- a. Describe the type, location, and results of measurements. Do any radiation levels exceed regulatory limits?

13. 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)**
- c. Did any overexposures and high radiation levels occur? Reported? **(12VAC5-481-1110)**
- d. If any events (as described in items a through c above) did occur, what was root cause? Were corrective actions appropriate?

14. POSTING AND LABELING

- a. VDH Form, 'Notice to Employees' posted? (12VAC5-481-2260 C)
- b. The agency regulations, license documents posted or a notice posted? (12VAC5-481-2260 A)
- c. Other posting and labeling? (12VAC5-481-850, 12VAC5-481-860, 12VAC5-481-880, 12VAC5-481-2260)

15. RECORD KEEPING FOR DECOMMISSIONING

- a. Records kept of information important to decommissioning? (12VAC5-481-450 C)
- b. Records include all information outlined (12VAC5-481-450 C)

16. BULLETINS AND INFORMATION NOTICES

- a. Are VDH's Information Notices received?
- b. Appropriate training and action taken in response?

17. SPECIAL LICENSE CONDITIONS OR ISSUES

- a. Did auditor review special license conditions or other issues (e.g., non-routine maintenance)?

18. 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. Are corrective actions planned or taken at ALL licensed locations (not just location audited)?
- c. Provide any other recommendations for improvement.

19. EVALUATION OF OTHER FACTORS

- a. Senior licensee management is appropriately involved with the radiation protection program and/or Radiation Safety Officer (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 G

Information Needed to Support Portable Gauge Licensee's Request to Perform Non-Routine Maintenance

Information Needed to Support Portable Gauge Licensee's Request to Perform Non-Routine Maintenance

Non-routine maintenance or repair (beyond routine cleaning and lubrication) involves detaching the source or source rod from the device and any other activities during which personnel could receive radiation doses exceeding VDH limits. If this maintenance or repair is not performed properly with attention to good radiation safety principles, the gauge may not operate as designed and personnel performing these tasks could receive radiation doses exceeding the VDH limits.

A typical moisture-density gauge contains 0.37 gigabecquerels (10 millicuries) of cesium-137 and 1.5 gigabecquerels (40 millicuries) of americium-241 as a neutron source. In about 9 minutes, an unshielded cesium-137 source of this activity can deliver 0.05 sievert (5 rems) to a worker's hands or fingers (i.e., extremities), assuming the extremities are 1 centimeter from the source. Some gauges contain sources of even higher activities with correspondingly higher dose rates. The threshold for extremity monitoring is 0.05 sievert (5 rems) per year.

Thus, applicants wishing to perform non-routine maintenance must use personnel with special training and follow appropriate procedures consistent with the manufacturer's instructions and recommendations that address radiation safety concerns (e.g., use of radiation survey meter, shielded container for the source, personnel dosimetry). Accordingly, provide the following information:

- Describe the types of work, maintenance, cleaning, repair, etc., to be performed that necessitate detaching the source or source rod from the device or that could cause personnel to receive radiation doses exceeding VDH limits. The principal reason for obtaining this information is to assist in the evaluation of the qualifications of individuals who will conduct the work and the radiation safety procedures they will follow.
- Identify who will perform non-routine maintenance, their training and experience, and why they are competent to perform non-routine maintenance.
- Submit procedures for safe handling of the radioactive source while the source or source rod is detached from the gauge. These procedures should ensure the following:
 - doses to personnel and members of the public are within regulatory limits and ALARA (e.g., use of shielded containers or shielding);
 - the source or source rod is secured against unauthorized removal access or under constant surveillance;
 - appropriate labels and signs are used; and
 - manufacturer's instructions and recommendations are followed.
- Confirm that individuals performing non-routine maintenance on gauges will always wear both whole body and extremity monitoring devices.
- Verify possession of at least one survey instrument meeting the following criteria:
 - Be capable of detecting gamma radiation;
 - Be capable of measuring from 0.01 to 0.5 mSv/hr (1 to 50 mrem/hr);

- Be calibrated at least annually with radionuclide point sources emitting radiation of the same type and energy of the sealed sources in the gauge;
- Be calibrated at least 2 points located at approximately 1/3 and 2/3 of each scale; readings within $\pm 20\%$ are acceptable;
- Be calibrated by a person specifically licensed by VDH, the NRC, or another Agreement State to calibrate radiation detection instruments; and
- Be checked for functionality prior to use (e.g., with the gauge or a check source).

Note: Records of instrument calibration must be maintained for 3 years after the record is made (**12VAC5-481-1000**).

- Describe steps to be taken to ensure that radiation levels in areas where non-routine maintenance will take place do not exceed **12VAC5-481-720** limits. For example, applicants can do the following:
 - commit to performing surveys with a survey instrument (as described above);
 - specify where and when surveys will be conducted during non-routine maintenance; and
 - commit to maintaining, for 3 years from the date of the survey, records of the survey (e.g., who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements), as required by **12VAC5-481-1050**.

Appendix H

Operating and Emergency Procedures

Operating Procedures

- If personnel dosimetry is provided:
 - Always wear your assigned OSL, TLD, or film badge when using the gauge or XRF.
 - Never wear another person's OSL, TLD, or film badge.
 - Never store your OSL, TLD, or film badge near the gauge.
- Before removing the gauge from its place of storage, ensure that, where applicable, each gauge source is in the fully shielded position and that in gauges with a movable rod containing a sealed source, the source rod is locked (e.g., keyed lock, padlock, mechanical control) in the shielded position. Place the gauge in the transport case and lock the case.
- Sign out the gauge or XRF in a log book (that remains at the storage location) including the date(s) of use, name(s) of the authorized users who will be responsible for the gauge, and the temporary jobsite(s) where the gauge will be used.
- Block and brace the gauge to prevent movement during transport and lock the gauge in or to the vehicle. Follow all applicable DOT requirements when transporting the gauge.
- Use the gauge or XRF according to the manufacturer's instructions and recommendations.
- Do not touch the unshielded source rod with your fingers, hands, or any part of your body.
- Do not place hands, fingers, feet, or other body parts in the radiation field from an unshielded source.
- Perform routine cleaning and maintenance according to the manufacturer's instructions and recommendations.
- When the gauge or XRF is not in use at a temporary jobsite, place the gauge or XRF in a secured location (e.g., locked in the trunk of a car or locked in a storage shed).
- Prior to transporting the gauge or XRF, ensure that, where applicable, each gauge source is in the fully shielded position. Ensure that, in gauges with a movable source rod, the source rod is locked in the shielded position (e.g., keyed lock, padlock, mechanical control). Place the gauge in the transport case and lock the case. Block and brace the case to prevent movement during transportation. Lock the case in or to the vehicle.
- Return the gauge or XRF to its proper locked storage location at the end of the work shift.
- Log the gauge or XRF into the daily use log when it is returned to storage.
- After making changes affecting the gauge storage area (e.g., changing the location of gauges within the storage area, removing shielding, adding gauges or XRFs, changing the occupancy of adjacent areas, moving the storage area to a new location), reevaluate compliance with public dose limits and ensure proper security of gauges or XRFs.

For Portable Gauges Only

- Unless absolutely necessary, do not look under the gauge when the source rod is being lowered into the ground. If you must look under the gauge to align the source rod with the hole, follow the manufacturer's procedures to minimize radiation exposure.
- After completing each measurement in which the source is unshielded, immediately return the source to the shielded position.
- Always maintain constant surveillance and immediate control of the gauge when it is not in storage. At job sites, do not walk away from the gauge when it is left on the ground. Take actions necessary to protect the gauge and yourself from danger of moving heavy equipment.
- Always keep unauthorized persons away from the gauge.
- If gauges are used for measurements with the unshielded source extended more than 3 feet beneath the surface, use piping, tubing, or other casing material to line the hole from the lowest depth to 12 inches above the surface. If the piping, tubing, or other casing material cannot extend 12 inches above the surface, cap the hole liner or take other steps to ensure that the hole is free of debris (and it is unlikely that debris will re-enter the cased hole) so that the unshielded source can move freely (e.g., use a dummy probe to verify that the hole is free of obstructions).

Emergency Procedures for Portable Gauges:

If the source fails to return to the shielded position (e.g., as a result of being damaged, source becomes stuck below the surface) or if any other emergency or unusual situation arises (e.g., the gauge is struck by a moving vehicle, is dropped, is in a vehicle involved in an accident):

- Immediately secure the area and keep people at least 15 feet away from the gauge until the situation is assessed and radiation levels are known. However, perform first aid for any injured individuals and remove them from the area only when medically safe to do so.
- If any heavy equipment is involved, detain the equipment and operator until it is determined there is no contamination present.
- Gauge users and other potentially contaminated individuals should not leave the scene until emergency assistance arrives.
- Notify the persons in the order listed below of the situation:

NAME*	WORK PHONE NUMBER*	HOME PHONE NUMBER*

* Fill in with (and update, as needed) the names and telephone numbers of appropriate personnel (e.g., the Radiation Safety Officer (RSO), or other knowledgeable licensee staff, licensee's consultant, gauge manufacturer) to be contacted in case of emergency.

Note: Telephone notifications shall be made to the agency at (804) 864-8150 during business hours, (804) 674-2400 or (800) 468-8892, which is staffed 24 hours/day. Identify the emergency as radiological.

Emergency Procedures for XRFs

If the XRF is lost, damaged or stolen, or if any other emergency or other unusual event occurs arises:

- Immediately secure the area and keep people at least 15 feet away from the XRF until the situation is assessed and radiation levels are known. However, perform first aid for any injured individuals and remove them from the area only when medically safe to do so.
- XRF users and other potentially contaminated individuals should not leave the scene until emergency assistance arrives.
- Notify the persons in order listed below of the situation:

NAME*	WORK PHONE NUMBER*	HOME PHONE NUMBER*

* Fill in with (and update, as needed) the names and telephone numbers of appropriate personnel (e.g., the Radiation Safety Officer (RSO), or other knowledgeable licensee staff, licensee's consultant, XRF manufacturer) to be contacted in case of emergency.

- Follow the directions provided by the person contacted above.

RSO and Licensee Management

- Arrange for a radiation survey to be conducted as soon as possible by a knowledgeable person using appropriate radiation detection instrumentation. This person could be a licensee employee using a survey meter located at the jobsite or a consultant. To accurately assess the radiation danger, it is essential that the person performing the survey be competent in the use of the survey meter.
- If portable gauges are used for measurements with the unshielded source extended more than 3 feet below the surface, contact persons listed on the emergency procedures who know the steps to be followed to retrieve a stuck source and to convey those steps to the staff on site.
- Make necessary notifications to local authorities as well as VDH as required. (Even if not required to do so, you may report ANY incident to the agency by calling **(804) 864-8150** during normal business hours. For immediate notifications after normal business hours, the 24 hour emergency telephone number is **(804) 674-2400** or **800-468-8892**. Identify the emergency as a radiological emergency. VDH notification is required when gauges containing licensed material are lost or stolen (**12VAC5-481-1090**), when gauges are damaged or involved in incidents that result in doses in excess of limits (**12VAC5-481-1100**, **12VAC5-481-1110**), and when it becomes apparent that attempts to recover a source stuck below the surface will be unsuccessful.

- Reports to VDH must be made within the reporting timeframes specified by the regulations.
- Reporting requirements are found in **12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, and 12VAC5-481-1150.**

Appendix I

Dosimetry-Related Guidance

Appendix I, Part 1

Worksheet for Demonstrating that Unmonitored Users Are Not Likely to Exceed 10 Percent of the Allowable Limits

Worksheet for Demonstrating that Unmonitored Individuals Are Not Likely to Exceed 10 Percent of the Allowable Limits

Instructions: To meet the requirement of 12VAC5-481-760 complete Steps 1 through 6 and sign and date the evaluation on the line provided.

Disclaimer: If there is a change in workload or if a new source is acquired a new evaluation will need to be performed.

Step 1.

Determine the radiation level while the shutter is open in one of the following ways. Record the results below.

- Obtain from the manufacturer's specifications: the radiation level approximately 30 centimeters from the portable gauge or XRF when shutter is open, or
- Measure the radiation level with a calibrated survey meter.

When making the radiation measurement while the shutter is open, place the survey instrument approximately 30 centimeters from the portable gauge or XRF while following good radiation safety practices.

_____ mrem per hour

Step 2.

Record the average number of minutes per week that the portable gauge or XRF is used with the shutter in open position.

_____ minutes per week

Step 3.

Divide the minutes per week (Step 2.) by 60 to determine hours per week and record below.

_____ minutes per week (Step 2.) / 60

= _____ hours per week

Step 4.

Multiply the hours per week (**Step 3.**) by 52 weeks to equal hours per year and record below.

$$\underline{\hspace{2cm}} \text{ hours per week (Step 3.)} \quad \times \quad 52 \text{ weeks}$$
$$= \underline{\hspace{4cm}} \text{ hours per year}$$

Step 5.

Multiply hours per year (**Step 4.**) by mrem per hour (**Step 1.**) to equal mrem received per year and record below.

$$\underline{\hspace{2cm}} \text{ hours per year (Step 4.)} \quad \times \quad \underline{\hspace{2cm}} \text{ mrem per hour (Step 1.)}$$
$$= \underline{\hspace{4cm}} \text{ mrem per year}$$

Step 6.

Is the # of mrem per year (**Step 5.**) greater than 500? Yes No

- If yes provide dosimetry as required by **12VAC5-481-760.**
- If no, proceed to **Step 7.**

Step 7.

Is the # of mrem per year (**Step 5.**) greater than 100? Yes No

- If yes, and you have an employee that is a declared pregnant worker, as defined by **12VAC5-481-10**, provide dosimetry to that individual. In addition, provide annual radiation safety training as required by **12VAC5-481-2270** to all employees that use the portable gauge or XRF.
- If no, you are not required under **12VAC5-481 'Virginia Radiation Protection Regulations'** to provide dosimetry to your employees.

Signature of Person Performing the
Evaluation

Date

Appendix I, Part 2

Guidance for Demonstrating that Individual Members of the Public will not Receive Doses Exceeding the Allowable Limits

Guidance for Demonstrating that Individual Members of the Public will not Receive Doses Exceeding the Allowable Limits

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 mSv (100 mrem) in one calendar year resulting from the licensee's possession and/or use of licensed materials.

Members of the public include persons who live, work, or may be near locations where portable gauges or XRFs are used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where gauges or XRFs are used or stored.

- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.

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

Licensees must show compliance with both portions of the regulation. Calculations or a combination of calculations and measurements (e.g., using an environmental film badge or OSL) are often used to prove compliance.

Calculation Method

Note: For ease of use by most portable gauge licensees, the examples in this Appendix use conventional units. The conversions to SI units are as follows: 1 ft = 0.305 m; 1 mrem = 0.01 mSv.

The calculation method takes a tiered approach, going through a three-part process starting with a worst case situation and moving toward more realistic situations. It makes the following simplifications: (1) each gauge is a point source, (2) typical radiation levels encountered when the source is in the shielded position are taken from either the Sealed Source & Device Registration (SSDR) Sheet or the manufacturer's literature, and (3) no credit is taken for any shielding found between the gauges and the unrestricted areas. Part 1 of the calculation method is simple but conservative. It assumes that an affected member of the public is present 24 hours a day and uses only the 'inverse square law' to determine if the distance between the gauge and the affected member of the public is sufficient to show compliance with the public dose limits. Part 2 considers not only distance, but also the time that the affected member of the public is actually in the area under consideration. Part 3 considers distance and the portion of time that both the gauge and the affected member of the public are present. Using this approach, licensees make only those calculations that are needed to demonstrate compliance. In many cases licensees will need to use the calculation method through Part 1 or Part 2. The results of these calculations typically result in higher radiation levels than would exist at typical facilities, but provide a method for estimating conservative doses which could be received.

Example 1

To better understand the calculation method, we will look at Moisture-Density Measurements, Inc., a portable gauge licensee. Yesterday, the company's president noted that the new gauge storage area is very close to his secretary's desk and he asked Joe, the Radiation Safety Officer (RSO), to determine if the company is complying with VDH regulations.

The secretary's desk is near the wall separating the reception area from the designated, locked gauge storage area, where the company is storing its three gauges. Joe measures the distances from each gauge to the wall and looks up in the manufacturer's literature the radiation levels individuals would encounter for each gauge.

Findings:

Joe finds that gauge #1 and #2 are stored in transportation containers, gauge #3 is not in a transport container as it is always being recharged. Gauge #1 is documented as reading 2 mrem/hr at 1 ft and is 8 ft away from the secretary's desk. Gauge #2 is documented as reading 8 mrem/hr at 1 ft and is 12 ft away from the secretary's desk. Gauge #3 is documented as reading 2 mrem/hr at 3 ft and is 15 ft away from the secretary's desk.

Example 1: Part 1

Joe's first thought is that the distance between the gauges and the secretary's chair may be sufficient to show compliance with the regulation in 12VAC5-481-720. So, taking a 'worst case' approach, he assumes: 1) the gauges are constantly present (i.e., 24 hr/d), 2) all three gauges remain in storage with no other use, and 3) the secretary is constantly sitting in the desk chair (i.e., 24 hr/d). Joe proceeds to calculate the dose she might receive hourly and yearly from each gauge as shown in Tables 3, 4, and 5 below.

Table 3, Calculation Method, Part 1---Hourly and Annual Dose Received from Gauge 1			
Step No.	Description	GAUGE 1	
		Input Data	Results
1	Dose received in an hour at known distance from gauge (e.g., from manufacturer's data), in mrem/hr	2	2
2	Square of the distance (ft) at which the Step 1 rate was measured, in ft ²	(1) ²	1
3	Square of the distance (ft) from the gauge to the secretary's desk in an unrestricted area, in ft ²	(8) ²	64
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	2 x 1 = 2	
5	Divide the result of Step 4 by the result of Step 3 to calculate the dose received by an individual at the secretary's desk, HOURLY DOSE RECEIVED FROM GAUGE 1 , in mrem in an hour.	2/64 = 0.031	
6	Multiply the result of Step 5 by 24 hr/d x 365 d/yr = MAXIMUM ANNUAL DOSE RECEIVED FROM GAUGE 1 , in mrem in a year.	0.031 x 24 x 365 = 0.031 x 8760 = 272	

Table 4, Calculation Method, Part 1--Hourly and Annual Dose Received from Gauge 2			
		GAUGE 2	
Step No.	Description	Input Data	Results
1	Dose received in an hour at known distance from gauge (e.g., from manufacturer's data), in mrem/hr	8	8
2	Square of the distance (ft) at which the Step 1 rate was measured, in ft ²	(1) ²	1
3	Square of the distance (ft) from the gauge to the secretary's desk in an unrestricted area, in ft ²	(12) ²	144
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	8 x 1 = 8	
5	Divide the result of Step 4 by the result of Step 3 to calculate dose received in an hour by an individual at the secretary's desk, HOURLY DOSE RECEIVED FROM GAUGE 2 , in mrem in an hour	8/144 = .056	
6	Multiply the result of Step 5 by 24 hr/d x 365 d/yr = MAXIMUM ANNUAL DOSE RECEIVED FROM GAUGE 2 , in mrem in a year	0.056 x 24 x 365 = 0.056 x 8760 = 491	

Table 5, Calculation Method, Part 1--Hourly and Annual Dose Received from Gauge 3			
		GAUGE 3	
Step No.	Description	Input Data	Results
1	Dose received in an hour at known distance from gauge (e.g., from manufacturer's data), in mrem/hr	2	2
2	Square of the distance (ft) at which the Step 1 rate was measured, in ft ²	(3) ²	9
3	Square of the distance (ft) from the gauge to the secretary's desk in an unrestricted area, in ft ²	(15) ²	225
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	2 x 9 = 18	
5	Divide the result of Step 4 by the result of Step 3 to calculate dose received by an individual at the secretary's desk, HOURLY DOSE RECEIVED FROM GAUGE 3 , in mrem in an hour	18/225 = 0.08	
6	Multiply the result of Step 5 by 24 hr/d x 365 d/yr = MAXIMUM ANNUAL DOSE RECEIVED FROM GAUGE 3 , in mrem in a year	0.08 x 24 x 365 = 0.08 x 8760 = 701	

To determine the total hourly and total annual dose received, Joe adds the pertinent data from the preceding tables.

Step No.	Description	Gauge 1	Gauge 2	Gauge 3	Sum
7	TOTAL HOURLY DOSE RECEIVED from Step 5 of Tables I-3, I-4, and I-5, in mrem in an hour	0.031	0.056	0.08	$0.031 + 0.056 + 0.08 = 0.167$
8	TOTAL ANNUAL DOSE RECEIVED from Step 6 of Tables I-3, I-4, and I-5, in mrem in a year	272	491	701	$272 + 491 + 701 = 1464$

Note: The Sum in Step 7 demonstrates compliance with the 2 mrem in any one hour limit. Reevaluate if assumptions change. If the Sum in Step 8 exceeds 100 mrem/yr, proceed to Part 2 of the calculation method.

At this point, Joe is pleased to see that the total dose that an individual could receive in any one hour is only 0.167 mrem, but notes that an individual could receive a dose of 1,464 mrem in a year, much higher than the 100 mrem limit.

Example 1: Part 2

Joe reviews his assumptions and recognizes that the secretary is not at the desk 24 hr/d. He decides to make a realistic estimate of the number of hours the secretary sits in the chair at the desk, keeping his other assumptions constant (i.e., the gauges are constantly present (i.e., 24 hr/d), all three gauges remain in storage with no other use). He then recalculates the annual dose received.

Step No.	Description	Results
9	A. Average number of hours per day that individual spends in area of concern (e.g., secretary sits at desk 5 hr/day; the remainder of the day the secretary is away from the desk area copying, filing, etc.)	5
	B. Average number of days per week in area (e.g., secretary is part time and works 3 days/week)	3
	C. Average number of weeks per year in area (e.g., secretary works all year)	52
10	Multiply the results of Step 9.A. by the results of Step 9.B. by the results of Step 9.C. = AVERAGE NUMBER OF HOURS IN AREA OF CONCERN PER YEAR	$5 \times 3 \times 52 = 780$
11	Multiply the sum in Step 7 by the results of Step 10 = ANNUAL DOSE RECEIVED FROM GAUGES CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN , in mrem in a year	$0.167 \times 780 = 130$

Note: If Step 11 exceeds 100 mrem in a year, proceed to Part 3 of the calculation method.

Although Joe is pleased to note that the calculated annual dose received is significantly lower, he realizes it still exceeds the 100 mrem in a year limit.

Example 1, Part 3

Again Joe reviews his assumptions and recognizes that the gauges are not always in storage when the secretary is seated at the desk. As he examines the situation, he realizes he must consider each gauge individually.

Summary of Information:

- Gauge #1 is located in the storage area continuously (24 hr/d).
- Gauge #2 is located in the storage area continuously (24 hr/d) for 8 months of the year and at temporary job sites for the remaining 4 months of the year.
- Gauge #3 is located in the storage area overnight only, it is used each day at temporary job sites and returned at the end of the day. The gauge is only present during the secretary's first and last hours of work each day.
- The secretary is sitting at the desk 5 hours/day, 3 days/week, and 52 weeks/year.

Step No.	Description	GAUGE 1	GAUGE 2	GAUGE 3
12	Average number of hours per day gauge is in storage while secretary is present	5	5	2
13	Average number of days per week gauge is in storage while secretary is present	3	3	3
14	Average number of weeks per year gauge is in storage while secretary is present	52	32	52
15	Multiply the results of Step 12 by the results of Step 13 by the results of Step 14 = TOTAL HOURS EACH GAUGE IS STORED PER YEAR WHILE SECRETARY IS PRESENT	$5 \times 3 \times 52 = 780$	$5 \times 3 \times 32 = 480$	$2 \times 3 \times 52 = 312$
16	Multiply the results of Step 15 by the results of Step 7 = ANNUAL DOSE RECEIVED FROM EACH GAUGE , in mrem in a year	$780 \times 0.031 = 24$	$480 \times 0.056 = 27$	$312 \times 0.08 = 25$
17	Sum the results of Step 16 for each gauge = TOTAL ANNUAL DOSE RECEIVED CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN AND TIME GAUGE IS IN STORAGE , in mrem in a year	$24 + 27 + 25 = 76$		

Note: If the result in Step 17 is greater than 100 mrem/yr, the licensee must take corrective actions.

Joe is pleased that the result in Step 17 shows compliance with the 100 mrem/yr limit. Had the result in Step 17 been higher than 100 mrem/yr, then Joe could have done one or more of the following:

- Consider whether the assumptions used to determine occupancy and the time each gauge is in storage are accurate, revise the assumptions as needed, and recalculate using the new assumptions

- Calculate the effect of any shielding located between the gauge storage area and the secretarial workstation - such calculation is beyond the scope of this Appendix
- Take corrective action (e.g., move gauges within storage area, move the storage area, move the secretarial workstation) and perform new calculations to demonstrate compliance
- Designate the area outside the storage area as a restricted area and the secretary as an occupationally exposed individual. This would require controlling access to the area for purposes of radiation protection and training the secretary as required by **12VAC5-481-2270**.

Note that in the example, Joe evaluated the unrestricted area outside only one wall of the gauge storage area. Licensees also need to make similar evaluations for other unrestricted areas and to keep in mind the ALARA principle, taking reasonable steps to keep radiation dose received below regulatory requirements. In addition, licensees need to be alert to changes in situations (e.g., moving any of the gauges closer to the secretarial workstation, adding a gauge to the storage area, changing the secretary to a full-time worker, or changing the estimate of the portion of time spent at the desk) and to perform additional evaluations, as needed.

Note: **12VAC5-481-1050** requires licensees to maintain records demonstrating compliance with the dose limits for individuals members of the public.

Combination Measurement-Calculation Method

This method, which allows the licensee to take credit for shielding between the gauge and the area in question, begins by measuring radiation levels in the areas, as opposed to using manufacturer-supplied rates at a specified distance from each gauge. These measurements must be made with calibrated survey meters sufficiently sensitive to measure background levels of radiation. However, licensees must exercise caution when making measurements with currently calibrated radiation survey instruments. A maximum dose of 1 mSv (100 mrem) received by an individual over a period of 2080 hours (i.e., a 'work' year of 40 hr/wk for 52 wk/yr) is equal to less than 0.5 microsievert (0.05 mrem) per hour.

This rate is well below the minimum sensitivity of most commonly available G-M survey instruments.

Instruments used to make measurements for calculations must be sufficiently sensitive. An instrument equipped with a scintillation-type detector (e.g., NaI(Tl)) or a micro-R meter used in making very low gamma radiation measurements should be adequate.

Licensees may also choose to use environmental film badges, TLDs, or OSLs in unrestricted areas next to the gauge storage area for monitoring. This direct measurement method would provide a definitive measurement of actual radiation levels in unrestricted areas without any restrictive assumptions. Records of these measurements can then be evaluated to ensure that rates in unrestricted areas do not exceed the 1 mSv/yr (100 mrem/yr) limit.

Note: TLDs used for personnel monitoring may not have sufficient sensitivity for this purpose. Generally, the minimum reportable dose received is 0.1 mSv (10 mrem). Suppose a TLD monitors dose received and is changed once a month. If the measurements are at the minimum reportable level, the annual dose received could have been about 1.2 mSv (120 mrem), a value in excess of the 1 mSv/yr (100 mrem/yr) limit. If licensees use TLDs to evaluate compliance with the public dose limits, they should consult with their supplier and choose more sensitive TLDs to be used for environmental monitoring.

Example 2

As in Example 1, Joe is the RSO for Moisture-Density Measurements, Inc., a portable gauge licensee. The company has three gauges stored in a designated, locked storage area that adjoins an unrestricted area where a secretarial work station is located. See Example 1, Findings paragraph. Joe wants to see if the company complies with the public dose limits at the secretarial station. During the winter while all the gauges were in storage, Joe placed an environmental TLD in the secretarial work space for 30 days. Joe chose a winter month so he did not have to keep track of the number of hours that each gauge was in the storage area. The TLD processor sent Joe a report indicating the film badge received 100 mrem.

Table 9, Combination Measurement-Calculation Method		
Step No.	Description	Input Data and Results
PART 1		
1	Dose received by TLD, in mrem	100
2	Total hours TLD exposed	24 hr/d x 30 d/mo = 720
3	Divide the results of Step 1 by the results of Step 2 to determine HOURLY DOSE RECEIVED , in mrem in an hour	0.14
4	Multiply the results of Step 3 by 365 d/yr x 24 hr/d = 8760 hours in one year = MAXIMUM ANNUAL DOSE RECEIVED FROM GAUGES , in mrem in a year	365 x 24 x 0.14 = 8760 x 0.14 = 1226
<p>NOTE: For the conditions described above, Step 3 indicates that the dose received in any one hour is less than the 2 mrem in any one hour limit. However, if there are any changes, then the licensee would need to reevaluate the potential doses which could be received in any one hour. Step 4 indicates that the annual dose received would be much greater than the 100 mrem in a year allowed by the regulations.</p>		
PART 2		
At this point Joe can adjust for a realistic estimate of the time the secretary spends in the area as he did in Part 2 of Example 1.		
PART 3		
If the results of Joe's evaluation in Part 2 show that the annual dose received in a year exceeds 100 mrem, then he can make adjustments for realistic estimates of the time spent in the area of concern while the gauges are actually in storage as in Part 3 of Example 1. (Recall that the TLD measurement was made while all the gauges were in storage--i.e., 24 hr/d for the 30 days that the TLD was in place.)		

Appendix J

Requests to Perform Leak Testing and Sample Analysis

Leak Test Program

Training

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

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

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

Appropriate on-the-job-training consists of:

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

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests will be analyzed in a low-background area.
- Individuals conducting leak tests will use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed.
- An NaI(Tl) well counter system with a single or multichannel analyzer will be used to count samples from gauges containing gamma-emitters (e.g., Cs-137, Co-60).
- A liquid scintillation or gas-flow proportional counting system will be used to count samples from gauges containing beta-emitters (e.g., Sr-90) or alpha emitters (e.g., Am-241).

Frequency for Conducting Leak Tests of Sealed Sources

- Leak tests will be conducted at the frequency specified in the respective SSDR Certificate.

Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as gauge serial number, radionuclide, and activity.
- If available, use a survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 185 Bq (0.005 microcurie) of the radionuclide contained in the gauge.
- Using the selected instrument, count and record background count rate.

- Check the instrument's counting efficiency using standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within +/-5 percent of the stated value and traceable to a primary radiation standard such as those maintained by the National Institutes of Standards and Technology (NIST).
- Calculate efficiency.

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

where: cpm = counts per minute
 std = standard
 bkg = background
 Bq = Becquerel

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

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

- Sign and date the list of sources, data, and calculations. Retain records for 5 years.
- If the wipe test activity is 185 Bq (0.005 microcurie) or greater, notify the RSO so that the source can be withdrawn from use and disposed of properly. Also notify VDH.

Appendix K

Major DOT Regulations; Sample Bill of Lading

Major DOT Regulations and Sample Bill of Lading

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

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

Portable gauges and XRFs are generally shipped either as excepted packages for limited quantities of radioactive material or as Type A packages. Packages containing XRFs may be shipped as limited quantities if the radiation level at any point on the external surface of the package does not exceed 0.005 mSv/hour (0.5 mrem/hour). Packages with higher radiation levels are shipped as Type A packages. The following tables summarize labeling, marking, and shipping paper requirements for Type A packages.

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.			
<ul style="list-style-type: none"> Labeling is required to be: (1) placed near the required marking of the proper shipping name, (2) printed or affixed to the package surface, (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. Two labels are required on opposite sides of the package, excluding the bottom. 			
Determination of Required Label			
Size: Sides: ≥ 100 mm Border: 5-6.3 mm			
	49 CFR 172.436	49 CFR 172.438	49 CFR 172.440
	WHITE-I	YELLOW-II	YELLOW-III
Required when:	Surface radiation level ≤ 0.005 mSv/hour (0.5 mrem/hour)	0.005 mSv/hour (0.5 mrem/hour) < surface radiation level ≤ 0.5 mSv/hour (50 mrem/hour)	0.5 mSv/hour (50 mrem/hour) < surface radiation level ≤ 2 mSv/hour (200 mrem/hour)
Or:	TI = 0 [1 meter dose rate < 0.5 mrem/hour]	TI ≤ 1 [1 meter dose rate ≤ 1 mrem/hour]	1 < TI ≤ 10 [1 meter dose rate ≤ 10 mrem/hour]
Content on Radioactive Labels			
RADIOACTIVE label must contain (entered using a durable, weather-resistant means): <ol style="list-style-type: none"> The radionuclides in the package. Symbols (e.g., Cs-137) are acceptable. The activity in SI units (e.g., Bq, TBq) or both SI units with customary units (e.g., Ci, mCi) in parenthesis. The Transport Index (TI) in the supplied box. The TI is entered only on YELLOW-II and YELLOW-III labels. 			
Some Special Considerations for Labeling Requirements			
<ul style="list-style-type: none"> Radioactive material, excepted packages (e.g., Limited Quantity, Radioactive Instrument and Article) are excepted from labeling. The "Cargo Aircraft Only" label is typically required for radioactive materials packages shipped by air [§172.402(c)] 			

Marking Packages (49 CFR 172.300-308)

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.

Always Required, Unless Excepted	Sometimes Required	Optional
<ul style="list-style-type: none"> • Proper shipping name • U.N. Identification Number • Name and address of consignor or consignee, unless: <ul style="list-style-type: none"> -Highway only and no motor carrier transfers, or -Part of truckload lot and entire contents of freight container are shipped from one consignor to one consignee (§172.301(d)) 	<ul style="list-style-type: none"> • If in excess of 50 kg, Gross Weight • If hazardous substance, "RQ" in association with the proper shipping name • The package type if Type A or Type B (1/2" or greater letters) • The specification-required markings (see §178.350-353) • For approved packages, the certificate ID number 	<ul style="list-style-type: none"> • Both the name and address of consignor and consignee are recommended. • Other markings (e.g., advertising) are permitted, but must be sufficiently away from markings and labeling

Some Special Considerations for Marking Requirements

- Marking is required to be (1) durable, (2) printed on a package, label, tag, or sign, (3) unobscured by labels or attachments, (4) isolated from other marks, and (5) be representative of the hazmat contents of the package.
- Limited quantity packages (§173.421) must bear the marking "radioactive" on the outside of the inner package, or the outer package itself, and are excepted from other marking.
- Empty (§173.428) and Radioactive Instrument and Article (§173.424) packages are excepted from marking.

DOT Shipping Papers (49 CFR 172.200-205)

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

Always Required, Unless Excepted	Sometimes Required
<ul style="list-style-type: none"> • The basic description, in sequence <ul style="list-style-type: none"> Proper shipping name Hazard Class (7) U.N. Identification Number • 24 hour emergency response telephone number • Name of shipper • Proper page numbering (Page 1 of 4) • The total quantity (mass), in appropriate units • The name of each radionuclide and total package activity. The activity must be in SI units (e.g., Bq, TBq) or both SI units and customary units (e.g., Ci, mCi). • For each labeled package: <ul style="list-style-type: none"> - The category of label used - The transport index of each package with a Yellow-II or Yellow-III label - Shipper's certification (not required of private carriers) 	<ul style="list-style-type: none"> • If hazardous substance, "RQ" as part of the basic description
	Optional
	<ul style="list-style-type: none"> • The type of packaging (e.g., Type A) • Other information is permitted (e.g., functional description of product), provided it does not confuse or detract from the proper shipping name or other required information • Emergency response hazards and guidance information (§§172.600-604) may be entered on the shipping papers, or may be carried with the shipping papers

Some Special Considerations/Exceptions for Shipping Paper Requirements

- Shipments of Radioactive Material, excepted packages, under UN2908-UN2911 (e.g., Limited Quantity, Empty, or Instrument and Article), are excepted from shipping papers. For limited quantities (§173.421), this is only true if the limited quantity is not a hazardous substance (RQ) or hazardous waste.
- Shipping papers must be in the pocket on the left door, or readily visible to a person entering the driver's compartment and within arm's reach of the driver.
- For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, be designated by an "X" (or "RQ") in the hazardous material column, or be highlighted in a contrasting color.

SAMPLE BILLS OF LADING

		DATE SHIP DATE	P.O. NO.	SHIPPER NO.	
CONSIGNEE RED E. WAITING		SHIPPER/CONSIGNOR (FROM) ABC PAVING COMPANY			
DEF PAVING INTERNATIONAL		456 MAIN STREET			
123 DIRT ROAD		ANY OTHER TOWN, USA 67890			
ANYTOWN, USA 12345					
PHONE NO.	EMERGENCY RESPONSE NUMBER (REQUIRED IN HM COLUMN MARKED) 123-456-7890			ROUTE	
Num ber of Pack ages	H M	Kind of Packaging, Description of Articles, Special Marks and Exceptions	Weight (lb)	Class or Rate Ref.	Cube (Optional)
1	x	RQ, Radioactive Material, Type A package,			
		Special Form, 7, UN3332			
		Cs-137, 0.30 GBq (8.0 mCi)			
		Am-241, 1.48 GBq (40 mCi)			
		Radioactive Yellow II Label, TI = 0.3			
		Dim 35 x 45 x 78 cm			
		Emergency Contact: (123) 456-7890			
THIS IS TO CERTIFY THAT THE ABOVE NAMES MATERIALS ARE PROPERLY CLASSIFIED, DESCRIBED, PACKAGED, MARKED, AND LABELED AND ARE IN PROPER CONDITION FOR TRANSPORTATION ACCORDING TO THE APPLICABLE REGULATIONS OF THE DEPARTMENT OF TRANSPORTATION.					
SHIPPER/CONSIGNOR WANDA SHIPPITT			CARRIER SB FREIGHTWAYS		
AUTHORIZED SIGNATURE DATE			AUTHORIZED SIGNATURE		

Your Company's Letterhead

BILL OF LADING

Shipper: ABS Paving Company
456 Main Street
Any town, USA

RQ, Radioactive material, Type A package,
Special Form, 7, UN 3332

CS-137, 0.30 GBq (8.0 mCi) Am-241, 1/48 GBq (40.0 mCi)

Radioactive Yellow II Label, TI = 0.3

*****EMERGENCY CONTACT: (123) 456-7890*****

(Signature)
SHIPPER

SAMPLE SHIPPERS DECLARATION FOR DANGEROUS GOODS

Shipper <div style="background-color: #cccccc; width: 100%; height: 40px;"></div>	Air Waybill No. <u>548974</u> Page of Pages Shipper's Reference Number <u>856</u>														
Consignee <u>APEX TESTING LABS</u> <u>355 MAIN STREET</u> <u>ATLANTA, GA</u> <u>USA</u>															
Two completed and signed copies of this Declaration must be handed to the operator															
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="2" style="text-align: left; padding: 2px;">TRANSPORT DETAILS</th> </tr> <tr> <td style="width: 30%; padding: 2px;"> This shipment is within the limitations prescribed for: <i>(delete non applicable)</i> </td> <td style="padding: 2px;"> Airport of Departure <div style="background-color: #cccccc; width: 100%; height: 15px;"></div> </td> </tr> <tr> <td style="padding: 2px;"> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; border-right: 1px solid black; padding: 2px;">PASSENGER AIRCRAFT</td> <td style="padding: 2px;">CARGO AIRCRAFT ONLY</td> </tr> </table> </td> <td style="padding: 2px;"></td> </tr> <tr> <td colspan="2" style="padding: 2px;"> Airport of Destination: <u>ATLANTA, HARTSFIELD</u> </td> </tr> </table>	TRANSPORT DETAILS		This shipment is within the limitations prescribed for: <i>(delete non applicable)</i>	Airport of Departure <div style="background-color: #cccccc; width: 100%; height: 15px;"></div>	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; border-right: 1px solid black; padding: 2px;">PASSENGER AIRCRAFT</td> <td style="padding: 2px;">CARGO AIRCRAFT ONLY</td> </tr> </table>	PASSENGER AIRCRAFT	CARGO AIRCRAFT ONLY		Airport of Destination: <u>ATLANTA, HARTSFIELD</u>		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 5px;"> WARNING Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. </td> </tr> <tr> <td style="padding: 2px;"> Shipment Type: <i>(delete non-applicable)</i> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%; border-right: 1px solid black; padding: 2px;">XXXXXXXXXXXXXX</td> <td style="padding: 2px;">RADIOACTIVE</td> </tr> </table> </td> </tr> </table>	WARNING Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.	Shipment Type: <i>(delete non-applicable)</i> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%; border-right: 1px solid black; padding: 2px;">XXXXXXXXXXXXXX</td> <td style="padding: 2px;">RADIOACTIVE</td> </tr> </table>	XXXXXXXXXXXXXX	RADIOACTIVE
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XXXXXXXXXXXXXX	RADIOACTIVE														
NATURE AND QUANTITY OF DANGEROUS GOODS <i>UN NUMBER OR IDENTIFICATION Number, Proper Shipping name, Class or Division (subsidiary risk), Packing Group (if required), and all other required information</i> UN 3332, Radioactive Material, Type A Package, Special Form, 7, RQ Cs-137, 0.30 GBq (8 mCi) Am-241, 1.48 GBq (40 mCi) All packed in one Type A package II-Yellow, TI = 0.6, Dim 35 x 42 x 75 cm															
<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">Additional Handling Information</td> <td>This shipment may be carried on passenger aircraft outside U.S. jurisdiction.</td> </tr> <tr> <td></td> <td style="text-align: center;">Emergency response sheet attached to Dangerous Goods Declaration</td> </tr> <tr> <td>Emergency Telephone Number</td> <td style="text-align: center;">(011) 123-456-7890</td> </tr> </table>		Additional Handling Information	This shipment may be carried on passenger aircraft outside U.S. jurisdiction.		Emergency response sheet attached to Dangerous Goods Declaration	Emergency Telephone Number	(011) 123-456-7890								
Additional Handling Information	This shipment may be carried on passenger aircraft outside U.S. jurisdiction.														
	Emergency response sheet attached to Dangerous Goods Declaration														
Emergency Telephone Number	(011) 123-456-7890														
I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labeled/placarded, and are in all respects in proper condition for transport according to applicable International and National Governmental Regulations. I declare that all of the applicable air transport requirements have been met	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">Name/Title of Signatory</td> <td style="padding: 2px;"><u>A. BROWN, SHIPPING MANAGER</u></td> </tr> <tr> <td style="padding: 2px;">Place and Date</td> <td style="padding: 2px;"><u>RICHMOND, VA JAN 1, 2007</u></td> </tr> <tr> <td style="padding: 2px;">Signature</td> <td style="padding: 2px;">(see warning above)</td> </tr> </table>	Name/Title of Signatory	<u>A. BROWN, SHIPPING MANAGER</u>	Place and Date	<u>RICHMOND, VA JAN 1, 2007</u>	Signature	(see warning above)								
Name/Title of Signatory	<u>A. BROWN, SHIPPING MANAGER</u>														
Place and Date	<u>RICHMOND, VA JAN 1, 2007</u>														
Signature	(see warning above)														

Appendix L

Security Guidance

Security Guidance

VDH regulations require a portable gauge licensee to use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal whenever the portable gauge **is not** under the control and constant surveillance by the licensee. “*Control and maintain constant surveillance*” of portable gauges means being immediately present or remaining in close proximity to the portable gauge to prevent unauthorized removal of the portable gauge. The objective of the security guidance is to reduce the opportunity for unauthorized removal and/or theft by providing a delay and deterrent mechanism.

The following security requirements apply to portable gauge licensees regardless of the location, situation, and activities involving the portable gauge. Licensees are required to either maintain control and constant surveillance of the portable gauge when in use or use two independent physical controls to secure the portable gauge from unauthorized removal while in storage. The physical controls used must be designed and constructed of materials suitable for securing the portable gauge from unauthorized removal, and both physical controls must be defeated in order for the portable gauge to be removed. Using two chains is not the preferred method; licensees are encouraged to use other combinations.

As long as the licensee maintains constant control and surveillance while transporting the portable gauges, the licensees need only to comply with the DOT requirements for transportation (e.g., placarding, labeling, shipping papers, blocking and bracing). However, if the licensee leaves the vehicle and portable gauge unattended (e.g., while visiting a gas station, restaurant, store), the licensee needs to ensure that the portable gauge is secured by two independent controls in order to comply with the requirements of **12VAC5-481-840 D**.

While transporting a portable gauge, a licensee should not modify the transportation case if it is being used as the Type A container for transporting the device. This includes, but is not limited to, drilling holes to mount the case to the vehicle or to mount brackets or other devices used for securing the case to the vehicle. In order to maintain its approval as a Type A shipping container, the modified package must be re-evaluated by any of the methods described in **49 CFR Part 178.350** or **173.461(a)**. The re-evaluation must be documented and maintained on file in accordance with DOT regulations.

Physical controls used may include, but are not limited to, a metal chain with a lock, a steel cable with a lock, a secured enclosure, a locked tool box, a locked camper, a locked trailer, a locked trunk of a car, inside a locked vehicle, a locked shelter, a secured fenced-in area, a locked garage, a locked non-portable cabinet, a locked room, or a secured building. To assist licensees, examples of two independent physical controls are provided below.

Securing a Portable Gauge at a Licensed Facility

When a portable gauge is stored at a licensed facility, the licensee is required to use two independent physical controls to secure the gauge. **Examples of two independent physical controls used to secure a portable gauge when stored at a licensed facility are --**

1. The portable gauge or transportation case containing the portable gauge is stored inside a locked storage shed within a secured outdoor area, such as a fenced parking area with a locked gate;
2. The portable gauge or transportation case containing the portable gauge is stored in a room with a locked door within a secured building for which the licensee controls access by lock and key or by a security guard;
3. The portable gauge or transportation case containing the portable gauge is stored inside a locked, non-portable cabinet inside a room with a locked door, if the building is not secured;
4. The portable gauge or transportation case containing the portable gauge is stored in a separate secured area inside a secured mini-warehouse or storage facility; or
5. The portable gauge or transportation case containing the portable gauge is physically secured to the inside structure of a secured mini-warehouse or storage facility.

Securing a Portable Gauge in a Vehicle

12VAC5-481 'Virginia Radiation Protection Regulations', Part XIII 'Transportation of Radioactive Material' requires that licensees who transport licensed material, or who may offer such material to a carrier for transport, must comply with the applicable requirements of the DOT that are found in **49 CFR Parts 170 through 189**.

Licensees commonly use a chain and a padlock to secure a portable gauge in its transportation case to the open bed of a pickup truck, while using the vehicle for storage. Because the transportation case is portable, a theft could occur if the chain is cut and the transportation case with the portable gauge is taken. If a licensee simply loops the chain through the handles of the transportation case, a thief could open the transportation case and take the portable gauge without removing the chain or the case. Similarly, because the transportation case is also portable, it must be protected by two independent physical controls if the portable gauge is inside. A lock on the transportation case, or a lock on the portable gauge source rod handle, is not sufficient because both the case and the gauge are portable.

A vehicle may be used for storage, however, it is recommended by the agency and DOT that this practice only be used for short periods of time or when a portable gauge is in transit. Storage in a hotel room is not authorized. When a portable gauge is being stored in a vehicle, the licensee is specifically required to use a minimum of two independent physical controls to secure the portable gauge.

Examples of two such independent physical controls approved by VDH to secure portable gauges in this situation are --

1. The locked transportation case containing the portable gauge is physically secured to a vehicle with brackets, and a chain or steel cable (attached to the vehicle) is wrapped around the transportation case such that the case can not be opened unless the chain or cable is removed;
2. The portable gauge or transportation case containing the portable gauge is stored in a box physically attached to a vehicle, and the box is secured with (1) two independent locks; (2) two separate chains or steel cables attached independently to the vehicle in such a manner that the box cannot be opened without the removal of the chains or cables; or (3) one lock and one chain or steel cable is attached to the vehicle in such a manner that the box cannot be opened without the removal of the chain or cable; or
3. The portable gauge or transportation case containing the portable gauge is stored in a locked trunk, camper shell, van, or other similar enclosure and is physically secured to the vehicle by a chain or steel cable in such a manner that one would not be able to open the case or remove the portable gauge without removal of the chain or cable.

Securing a Portable Gauge at a Temporary Jobsite or at Locations Other Than a Licensed Facility

When a job requires storage of a portable gauge at a temporary jobsite or at a location other than a licensed facility, the licensee should use a permanent structure for storage, if practicable.

When storing a portable gauge at a temporary jobsite, the licensee should limit access by storing the gauge as far away from members of the public as possible. The licensee must also meet the radiation exposure limits specified in **12VAC5-481-720**. When a portable gauge is stored at a temporary jobsite or at a location other than an authorized facility, the licensee is required to use two independent physical controls to secure the portable gauge. **Examples of two independent physical controls to secure portable gauges at these locations are --**

1. At a temporary job site, the portable gauge or transportation case containing the portable gauge is stored inside a locked building or in a locked non-portable structure (e.g., construction trailer, sea container, etc.), and is physically secured by a chain or steel cable to a non-portable structure in such a manner that an individual would not be able to open the transportation case or remove the portable gauge without removing the chain or cable. A lock on the transportation case or a lock on the portable gauge source rod handle would not be sufficient because the case and the portable gauge are portable;
2. The portable gauge or transportation case containing the portable gauge is stored in a locked garage, and is within a locked vehicle or is physically secured by a chain or steel cable to the vehicle in such a manner that an individual would not be able to open the transportation case or remove the portable gauge without removing the chain or cable; or
3. The portable gauge or transportation case containing the portable gauge is stored in a locked garage, and is within a locked enclosure or is physically secured by a chain or steel cable to a permanent or non-portable structure in such a manner that an individual would not be able to open the transportation case or remove the portable gauge without removing the chain or cable.

Appendix M

**VDH Form
'Certificate of Disposition of Materials'**



CERTIFICATE OF DISPOSITION OF MATERIALS

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

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

CONTACT INFORMATION

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

TERMINATION AND DISPOSITION INFORMATION

The following information is provided in accordance with 12VAC5-481-510. (Check all that apply)

- Item 4** All use of radioactive material authorized under the above referenced license has been terminated.
- Item 5** Radioactive contamination has been removed to the levels outlined in 12VAC5-481-1161 B.
- Item 6** All radioactive material previously procured and/or possessed under the authorization granted by the above referenced license has been disposed of as follows. (Check all that apply)
 - Transferred to: Name Address

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

Issued by (Licensing Agency):

- Decayed, surveyed and disposed of as non-radioactive waste.
- No radioactive material has ever been procured and/or possessed by the licensee under the authorization granted by the above referenced license.
- Other (Attach additional pages)

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

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

Name:

Address:

Contact Person Telephone Number: () - X

Additional remarks (Attach additional pages if necessary.)

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

Item 10.

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

SIGNATURE - Applicant or Authorized Individual

Date signed

Print Name and Title of Above Signatroy

Appendix N

Model Delegation of Authority (RSO)

Memo to: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with the rule. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Virginia Department of Health, Radioactive Materials Program at anytime. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

Signature of Management Representative

I accept the above responsibilities,

Signature of Radiation Safety Officer

cc: Affected department heads.

Commonwealth of Virginia
Radiation Protection Regulatory Guide



Guidance for Industrial Radiography Use

EPI-720 B

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

EXECUTIVE SUMMARY

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

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

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

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

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

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

In summary, the applicant will need to perform the following to submit an application for an Industrial Radiography license:

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

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

Please identify all attachments with the applicant's name and license number (if a renewal).

- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original signed application along with attachments (if any).
- Submit the application fee (for new licenses only).
- Retain one copy of the licensee application and attachments (if any) for your future reference. You will need this information because the license will require that radioactive material be possessed and used in accordance with statements, representation, and procedures provided in the application and supporting documentation.

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

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ABBREVIATIONS

ALARA	as low as reasonably is achievable
ANSI	American National Standards Institute
ALI	annual limit on intake
Bq	Becquerel
CFR	Code of Federal Regulations
Ci	Curie
cm	centimeter
cm ²	centimeter squared
cpm	counts per minute
COC	Certificate of Compliance
DOE	United States Department of Energy
DOT	United States Department of Transportation
dpm	disintegrations per minute
DU	Depleted uranium
hr	Hour
GM	Geiger-Mueller
IN	Information Notice
mCi	millicurie
mR	milliroentgen
mrem	Millirem
mSv	Millisievert
NARM	Naturally-occurring and Accelerator-produced Radioactive Material
NIST	National Institute of Standards and Technology
NMSS	Office of Nuclear Materials Safety and Safeguards
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OSL	optically stimulated luminescence dosimeter
RG	Regulatory Guide
RQ	Reportable quantities
RSO	Radiation Safety Officer
SI	International System of Units (abbreviated SI from the French Le Systeme Internationale d'Unites)
SSD	Sealed Source and Device
SSDR	Sealed Source and Device Registry
Sv	Sievert
TEDE	Total effective dose equivalent
TI	Transportation Index
TLD	Thermoluminescent dosimeters
VDH	Virginia Department of Health
μCi	microcurie
%	percent

PURPOSE OF GUIDE

This document provides guidance to an applicant in preparing a license application for Industrial Radiography. It also provides guidance on VDH's criteria for evaluating an Industrial Radiography license application. It is not intended to address the research and development of radiography devices or associated equipment, or the commercial aspects of manufacturing, distribution, and service of such devices or equipment. The term 'radiography' as used in this guide means an examination of the structure of materials by nondestructive methods, using ionizing radiation to make radiographic images generally using gamma-emitting radioactive materials (radioisotopes). The radioisotopes most commonly used for radiography are cobalt-60 and iridium-192; however, other radioisotopes (e.g. californium-252) with unique radiological characteristics may also be used.

This guide identifies the information needed to complete VDH Form, 'Application for a Radioactive Material License Authorizing the Use of Industrial Radiography' (**Appendix A**).

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

- **Rule** - references the requirements from **12VAC5-481 'Virginia Radiation Protection Regulations'** applicable to the item;
- **Criteria** - outlines the criteria used to judge the adequacy of the applicant's response;
- **Discussion** - provides additional information on the topic sufficient to meet the needs of most readers;
- and
- **Response from Applicant** - shows the appropriate item on the application and provides: response(s), offers the option of an alternative response, or indicates that no response is needed on that topic.

The information submitted in the application must be sufficient to demonstrate that proposed equipment, facilities, personnel, and procedures are adequate to protect the health and safety of the citizens of the Commonwealth of Virginia in accordance with agency guidelines.

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

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

In this guide, "dose" or "radiation dose" means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent (TEDE). These terms are defined in the **12VAC5-481-10**. Rem and Sievert (Sv), its SI equivalent (1 rem = 0.01 Sv), are used to describe units of radiation exposure or dose. These units are used because **12VAC5-481 '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.

The VAREG provides the latest guidance and is modeled on the Nuclear Regulatory Commission's (NRC) NUREG 1556, Volume 2. The VAREG shows the requirements in terms of the **12VAC5-481 'Virginia Radiation Protection Regulations'** and provides a user-friendly format to assist with the preparation of a Industrial Radiography license application.

LICENSES

Applicants should study this document, related guidance, and all applicable regulations carefully before completing the VDH Form 'Application for a Radioactive Material License Authorizing the Use of Industrial Radiography'. 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, environmental health officer, district office staff) to help determine the jurisdictional status of the land and to provide the information in writing, so that licensees can comply with VDH or NRC regulatory requirements, as appropriate. The following table lists examples of regulatory authority.

Table 1: Who Regulates the Activity?

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

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

MANAGEMENT RESPONSIBILITY

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

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

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

- Radiation protection, security, and control of radioactive materials, and compliance with rule;
- Knowledge about the contents of the license application;
- Compliance with current VDH and United 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;
- Confirming that the RSO has independent authority to stop unsafe operations and will be given sufficient time to fulfill his/her radiation safety duties and responsibilities;
- Ensuring worker audits are conducted at 6-month intervals (may be performed by the RSO);
- Ensuring workers have had adequate training;
- Reporting equipment failures as required under **12VAC5-481-1530**; and
- Ensuring current, up-to-date VDH and DOT rules and regulations are available to all employees.

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

APPLICABLE RULE

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

The following Parts of **12VAC5-481 'Virginia Radiation Protection Regulations'** contain requirements applicable to Industrial Radiography licensees:

- Part I 'General Provisions'
- Part III 'Licensing of Radioactive Material'
- Part IV 'Standards for Protection Against Radiation'
- Part V 'Radiation Safety Requirements for Industrial Radiographic Operations'
- Part X 'Notices, Instructions and Reports to Workers; Inspections'
- 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 Authorizing the Use of Industrial Radiography' (**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 8-1/2 x 11 inch paper.
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original, signed application.
- Retain one copy of the license application for your future reference.

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

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

WHERE TO FILE

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

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

LICENSE FEES

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

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

Direct all questions about VDH's fees or completion of **Item 12** of VDH Form, 'Application for a Radioactive Material License Authorizing the Use of Industrial Radiography' (**Appendix A**) to: **Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219 or (804) 864-8150.**

CONTENTS OF APPLICATION

Item 1: Type of Application

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

Response from Applicant:

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

Item 2: Name and Mailing Address of Applicant

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

Notify the agency of changes in the mailing address.

Response from Applicant:

Item 2 Name And Mailing Address Of Applicant: <hr/> Applicant's Telephone Number (Include area code):
--

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

Timely Notification of Change of Ownership or Control

Rule: 12VAC5-481-330, 12VAC5-481-500 B

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

Discussion: Changes in ownership may be the results of mergers, contractual agreements, 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 license issued by VDH, the NRC, or another Agreement state;
- Materials are properly handled and secured;
- Persons using these materials are competent and committed to implementing appropriate radiological controls;
- A clear chain of custody is established to identify who is responsible for final disposal of radiography devices; and
- Public health and safety are not compromised by the use of such materials.

Note: Appendix E identifies the information to be provided about transfer of control.

Notification of Bankruptcy Proceedings

Rule: 12VAC5-481-500

Criteria: Immediately following filing of voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify VDH in writing, identify the bankruptcy court in which the petition was filed and the date of filing.

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

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

Item 3: Person To Contact Regarding Application

Criteria: Identify the individual who can answer questions regarding the application and include their telephone number. This is typically the proposed RSO or knowledgeable management official. The agency will contact this individual if there are any questions about this application.

Discussion: Notify the agency if the contact person or telephone number changes. This notice is 'for information only' and does not require a license amendment fee.

Response from Applicant:

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

Item 4: Location of Radioactive Material

Rule: 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-590, 12VAC5-481-1200 A, 12VAC5-481-1530 C

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

Discussion: Specify the street address, or other descriptive address (such as on Highway 17, 5 miles east of the intersection of Highway 17 and State Route 234), city and zip code for each permanent storage or use facility and field station. A field station is a location where licensed material may be stored or used, and from which the applicant will dispatch equipment to jobsites. **A Post Office Box address is not acceptable because the agency needs a specific address to allow an inspector to find the use and/or storage location.** If devices will NOT be stored at a dispatch site or field station, indicate this. The applicant should indicate whether a location will be used to perform radiographic operations, storage of sources and devices or used and stored. The applicant should indicate if a permanent cell is located at the address.

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

Response from Applicant:

Item 4 Location of Radioactive Material (Do not use Post Office Box):		
<input type="checkbox"/> Used <input type="checkbox"/> Stored <input type="checkbox"/> Used and Stored	Address: <input type="checkbox"/> Permanent Cell Facility	Telephone Number (Include area code):
<input type="checkbox"/> Used <input type="checkbox"/> Stored <input type="checkbox"/> Used and Stored	Address: <input type="checkbox"/> Permanent Cell Facility	Telephone Number (Include area code):
<input type="checkbox"/> Used <input type="checkbox"/> Stored <input type="checkbox"/> Used and Stored	Address: <input type="checkbox"/> Permanent Cell Facility	Telephone Number (Include area code):
Is industrial radiography performed at temporary job sites?: <input type="checkbox"/> Yes <input type="checkbox"/> No		

Note: If radiography operations are expected to exceed 180 days at a temporary jobsite, then provide written notification to the agency prior to exceeding the 180 days (a license amendment is not required).

Item 5: Radiation Safety Officer (RSO)

Rule: 12VAC5-481-450 A, 12VAC5-481-630, 12VAC5-481-1200, 12VAC5-481-1310

Criteria: RSOs and potential designees are responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures, and must have adequate training and experience.

Discussion: The person responsible for the radiation protection program is called the RSO. The agency believes the RSO is the key to overseeing and ensuring safe operation of the licensee's radiography program. The RSO needs independent authority to stop operations that he or she considers unsafe. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure radioactive materials are used in a safe manner. Typical RSO duties are illustrated in **Table 2**.

The RSO may delegate certain day-to-day tasks of the radiation protection program to other responsible individuals (potential designees). For example, a large testing company with multiple field stations may appoint individuals designated as 'site RSOs' who assist the RSO and are responsible for the day-to-day activities at the field stations. Licensees may also appoint other individuals who may 'step-in' as an emergency contact when the RSO is unavailable. The potential designees do not need to meet the required RSO qualifications; however, these individuals should be qualified, experienced radiographers who are adequately knowledgeable of the activities to which they are assigned. Applicants do not have to identify other responsible individuals if day-to-day tasks, etc. will not be delegated.

VDH requires the name of the RSO on the license to ensure that licensee management has identified a responsible, qualified person and that the named individual knows their designation as RSO. Provide the agency with a copy of an organizational chart showing the RSO and other designated responsible individuals, to demonstrate they have sufficient independence and direct communication with responsible management officials. Also show in the organizational chart the position of the individual who signs **Item 13** of the 'Application for a Radioactive Material License Authorizing the use of Industrial Radiography' (**Appendix A**).

To be considered eligible for the RSO position, an individual must be a qualified radiographer, have a minimum of 2,000 hours (one-year full-time field experience) of hands-on experience as a qualified radiographer, and have formal training in establishing and maintaining a radiation protection program. This should be a course specifically designed to provide training in running a radiation safety program, a basic radiation safety course is not acceptable. While a course particular to industrial radiography would be highly encouraged, this is not required. Hands-on experience means experience in all areas considered to be directly involved in the radiography process, this includes taking radiographs, surveying devices, transporting the radiography equipment to temporary jobsites, posting, work sites, radiation area surveillance, and completing and maintaining records. Excessive time spent in only one or two of these operations (film development and/or area surveillance) should not be counted toward the 2,000 hours. Experience with radiography using x-rays can be included; however, the majority of experience should be in isotope radiography.

The agency will consider individuals with alternative training and experience as RSOs. For example, a person certified in health physics or industrial hygiene with previous experience in managing a radiation safety program of comparable size and scope could be considered on an individual case. The qualifications, training, and experience required of the RSO may vary depending upon the complexity of the applicant's operations and number of radiography personnel.

Table 2: Radiation Safety Officer Duties and Authorities

Radiation Safety Officer Duties and Authorities
1. Establish and oversee all operating, emergency, and ALARA procedures and review them regularly.
2. Oversee and approve the training program for radiographic personnel.
3. Ensure required radiation surveys and leak test are performed and documented including any corrective measures taken.
4. Ensure personnel monitoring devices are calibrated and used properly, and that records are kept of results and timely notifications are made.
5. Operations are conducted safely and corrective actions are implemented, when necessary, including terminating operations.
Above all, the RSO is the key to maintaining the radiation safety of the operations to the workers, the public, and the environment.

Response from Applicant:

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

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

NAME: _____ TELEPHONE NUMBER: _____
 (Include area code)

AND

We will demonstrate that the RSO has sufficient independence and direct communication with responsible management officials by providing a copy of an organizational chart by position and will confirm that the RSO has day-to-day oversight of the radiation safety activities.

AND EITHER

We will provide the specific training and experience of the RSO. Including the following:

1. Specific dates of certification and/or training in radiation safety.
2. Documentation to show that the RSO has a minimum of 2,000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations.
3. Documentation to show that the RSO has obtained formal training in the establishment and maintenance of a radiation protection program.

OR

We will provide alternative information demonstrating that the proposed RSO is qualified by training and experience (e.g. Board Certification by the American Board of Health Physicists, completion of a bachelor's and/or master's degree in the sciences with at least one year of experience in the conduct of a radiation safety program of comparable size and scope) documentation to show that the RSO has obtained formal training in the establishment and maintenance of a radiation protection program.

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

Item 6: Training for Radiographers and Radiographer's Assistants

Rule: 12VAC5-481-450 A, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-1200, 12VAC5-481-1320, 12VAC5-481-2260, 12VAC5-481-2270, 12VAC5-481-2280, 12VAC5-

481-2310

Criteria: Radiographers and radiographer's assistants must have adequate training and experience as outlined in **12VAC5-481-1320**.

Discussion:

- A radiographer is a person who performs or personally supervises industrial radiography and is responsible for ensuring compliance with VDH rules and the safe use of radioactive materials.
- A certified radiographer is an individual who has been certified by a certifying entity such that he/she has met established radiation safety, testing, and experience criteria.
- A radiographer's assistant is an individual, who under the direct supervision (in the physical presence) of the radiographer uses radiographic equipment in performing industrial radiographic operations.

12VAC5-481-1320 describes specific training requirements for radiographers and radiographer's assistants and requires that all radiographers be certified. It also addresses annual refresher training and semiannual audits of radiographers and radiographer's assistants.

Refer to **Appendix G** as an aid to determining the specific training requirements for radiographers and radiographer's assistants. The applicant must submit a description of their training program for radiographers and radiographer's assistants.

Because **12VAC5-481-1320** contains different requirements for radiographers and radiographer's assistants, include training programs for each. When describing the training programs for these positions, include the sequence of events from the time of hiring through the designation of individuals as radiographers or radiographer's assistants. Experienced radiographers who have worked for another licensee should receive formal instruction similar to that given to prospective radiographer's assistants. This instruction must include training in your operating and emergency procedures, in the use of your exposure devices and associated equipment, and in the use of survey meters and other radiation monitoring devices.

Instructors who provide classroom training to individuals in the principles of radiation and radiation safety should have knowledge and understanding of these principles beyond those obtainable in a course similar to the one given to prospective radiographers. Individuals who provide instruction in the hands-on use of radiography equipment should be qualified radiographers with at least 1 year of experience in performing radiography, or should possess a thorough understanding of the operation of radiographic equipment (e.g., a manufacturer's service representative).

An internal inspection program (audit program) of the job performance of each radiographer and radiographer's assistant ensures that VDH's rules, license requirements, and the licensee's operating and emergency procedures are followed. The audit must include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation at intervals not to exceed 6 months. If a radiographer or radiographer's assistant has not participated in an industrial radiographic operation for more than 6 months, the individual must demonstrate knowledge of the training requirements by practical examination before participating in a radiographic operation. The person conducting internal inspections should have a minimum of one-year actual experience as a radiographer.

The applicant shall:

- Submit an outline of the training to be given to prospective radiographer's assistants.

Submit your procedures for experienced radiographers who have worked for another licensee.

- Specify the qualifications of your instructors in radiation safety principles and describe their experience with radiography. If training will be conducted by someone outside the applicant's organization, identify the course by title and provide the name and address of the company providing the training.
- Describe the field (practical) examination that will be given to radiographer's assistants. The agency suggests using the checklist in **Appendix H** as a source of potential areas to review during the field examination.
- Describe the annual refresher training program, including topics to be covered and how the training will be conducted.
- Submit your procedures for verifying and documenting the certification status for verifying that their certification remains valid. As a minimum your procedures for newly hired, previously certified individuals should require documentation of your contacting the certifying entity and confirming the certification. Your procedures should also ensure you are aware of certification expiration dates and that individuals with expired certifications do not act a radiographers.
- Submit a description of your program for inspecting the job performance of each radiographer and radiographers' assistant at intervals not to exceed 6 months as described in **12VAC5-481-1320 E**.

Response from Applicant:

Item 6 Training For Radiographers and Radiographer's Assistants (Check box and attach requested information)

- We will submit the information outlined in section titled 'Training for Radiographers and Radiographer's Assistants' in VAREG 'Guidance for Industrial Radiography Use'.

Note: X-ray training by itself will not be considered adequate experience for performing gamma radiography.

Radioactive Material

Item 7: Sealed Source Radioactive Material

Rule: 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-1210, 12VAC5-481-1400

Criteria: Applicants must provide the manufacturer's (or distributor's) name and model number for each requested source assembly (sealed source), exposure device, and source changer. Licensees will only be authorized for radiographic exposure devices, source assemblies or sealed sources containing radioactive material and associated equipment meeting VDH performance requirements and specifically approved or registered by the NRC or another Agreement State. Also, identify any depleted uranium that is used as shielding material (radiographic exposure devices, source changers and some collimators contain depleted uranium).

Discussion: The NRC or another Agreement State performs a safety evaluation of radiography source assemblies (sealed sources) exposure devices and source changers prior to distribution of these sources/devices to specific licensees. The safety evaluation is documented in a Sealed

Source and Device Registration (SSDR) Certificate issued to the manufacturer (or distributor). Therefore, if the source assemblies, exposure devices, or source changers are approved for use by the NRC or another Agreement State, the applicant need only note the manufacturer's (or distributor's) name and model number of the sources/devices in its license application to demonstrate that the requirements are met.

SSDR Certificates contain sections on "*Conditions of Normal Use*" and "*Limitation and Other Considerations of Use*". These sections may include limitations derived from conditions imposed by the manufacturer or distributor, by particular conditions of use that would reduce radiation safety of the device, or by circumstances unique to the sealed source or device. 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 SSDR 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 SSDR.

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

Consult with the manufacturer of the associated equipment (i.e., equipment that is used in conjunction with the exposure device that drives, guides, or comes in contact with the source) to be sure that the associated equipment is compatible with the sources and devices. Licensees must demonstrate that associated equipment meets the performance requirements in **12VAC5-481-1210** that are equivalent to **10 CFR 34.20**. NRC Regulatory Issue Summary (RIS) 2005-10, 'Performance-Based Approach For Associated Equipment in 10 CFR 34.20' (**Appendix F**) alerts licensees to distinguish between items of equipment that are not. For example, the portion of the connector that is attached to the end of the control cable is actually a component of the source assembly and is subject to the safety evaluation that must be completed by the NRC or another Agreement State before the source assembly may be specifically authorized for use by a licensee. NRC RIS 2005-10 also contains a number of ways that licensees can demonstrate that their associated equipment meets the performance requirements stated in **12VAC5-481-1210**.

Response from Applicant:

Item 7 Sealed Source Radioactive Material (Attach additional pages if necessary)	
Element and mass number	Sealed source manufacturer and model number
Maximum activity per source	Exposure device manufacturer and model number
Source changer manufacturer and model number	
Is Depleted Uranium used as a shielding material? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Only radiographic exposure devices, source assemblies or sealed sources, and associated equipment which meets the requirements specified in 12VAC5-481-1210 will be used in radiographic operations. <input type="checkbox"/> Yes <input type="checkbox"/> No	

Note: The following tables list several devices with associated radionuclides and amounts:

Table 3: Industrial Nuclear Model Ir-100 Exposure Device Maximum Authorization -- 120 Ci

Element	Sealed Source	Curies	Source Changer Meeting 10 CFR 34 Requirements	Maximum Curies Authorized
Ir-192	IN Model 32	120 Ci	Amersham 550-SU IN IR-50	120 Ci 120 Ci
Ir-192	IN Model 33	120 Ci	Amersham 550 -SU IN IR-50	120 Ci 120 Ci
Ir-192	Amersham 87703	120 Ci	Amersham 550 -SU Amersham 650L Amersham 820 Amersham 855 IN IR-50	120 Ci 240 Ci 1,000 Ci 960 Ci 120 Ci
Ir-192	Amersham 87704	120 Ci	Amersham 550 -SU Amersham 650 Amersham 820 Amersham 855	120 Ci 240 Ci 1,000 Ci 960 Ci
Ir-192	SPEC G-40F	120 Ci	Amersham 550 -SU SPEC C-1 IN IR-50	120 Ci 150 Ci 120 Ci
Ir-192	SPEC G-40T	120 Ci	Amersham 550 -SU SPEC C-1 IN IR-50	120 Ci 150 Ci 120 Ci

Table 4: Spec Model 150 Exposure Device Maximum Authorization -- 150 Ci

Element	Sealed Source	Curies	Source Changer	Curie Authorization
Ir-192	SPEC G-60	240 Ci	SPEC C-1	150 Ci

Table 5: Amersham Model 680 System Exposure Device Maximum Authorization -- 110 Ci

Element	Sealed Source	Curies	Source Changer	Curie Authorization
Co-60	Amersham A424-14	110 Ci	Amersham 770 Amersham 771	550 Ci 110 Ci
Co-60	Amersham 943	110 Ci	Amersham 770 Amersham 771	550 Ci 110 Ci

Table 6: Amersham Model 660 System Exposure Device Maximum Authorization -- 140 Ci

Element	Sealed Source	Curies	Source Changer	Curie Authorization
Ir-192	IN Model 7	100 Ci	Amersham 550 -SU Amersham 650L Amersham 820 Amersham 855 IN IR-50 SPEC C-1	120 Ci 240 Ci 1,000 Ci 960 Ci 120 Ci 150 Ci
Ir-192	CIS-US 702	120 Ci	Amersham 550 -SU IN IR-50 SPEC C-1	120 Ci 120 Ci 150 Ci
Ir-192	Amersham 91813	20 Ci	Amersham 650L	240 Ci
Ir-192	Amersham A424-22	240 Ci	Amersham 550 -SU Amersham 650L Amersham 820 Amersham 855	120 Ci 240 Ci 1,000 Ci 960 Ci
Ir-192	Amersham A424-9	240 Ci	Amersham 550 -SU Amersham 650L Amersham 820 Amersham 855 IN IR-50 SPEC C-1	120 Ci 240 Ci 1,000 Ci 960 Ci 120 Ci 150 Ci

Item 8: Financial Assurance and Recordkeeping for Decommissioning

Rule: 12VAC5-481-100, 12VAC5-481-450 C, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-1161

Criteria: Industrial radiography licensees authorized to possess sealed sources containing radioactive material in excess of the limits specified in 12VAC5-481-450 C must provide evidence of financial assurance for decommissioning.

Licensees are required to maintain, in an identified location, decommissioning records related to structures and equipment where devices are used or stored and records related to leaking sources. Licensees must transfer these records important to decommissioning either to any new licensee before licensed activities are transferred or assigned in accordance with 12VAC5-481-500 B, or to the agency before license is terminated.

Discussion: The requirements for financial assurance are specific to the types and quantities of radioactive material authorized on a license. Most industrial radiography applicants and licensees do not need to comply with the financial assurance requirements because the thresholds for sealed sources containing radioactive material are 3.7×10^5 Bq (10,000 curies) of cobalt-60 and 3.7×10^6 Bq (100,000 curies) of cesium-137 or radioactive material with half-lives less than 120 days (e.g., iridium-192). Thus, a licensee would need to possess hundreds of sources before the financial assurance requirements would apply. Since the standard industrial radiography license does not specify the maximum number of sources that the licensee may possess (allowing the licensee flexibility in obtaining sources/devices as needed without amending its license), it contains a condition requiring the licensee to limit its possession of sources to quantities not requiring financial assurance for decommissioning. Applicants and licensees desiring to possess sources exceeding the threshold amounts must submit evidence of financial assurance.

The same rule also requires that licensees maintain records important to decommissioning in an identified location. All industrial radiography 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 radiography 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.

Response from Applicant:

Item 8 Financial Assurance And Recordkeeping For Decommissioning (Check both boxes)

We shall maintain drawings and records important to decommissioning and will transfer these records to a new licensee before licensed activities are transferred in accordance with 12VAC5-481-500 B or assign the records to the agency before the license is terminated.

AND

If financial assurance is required, submit evidence per 12VAC5-481-450 C.

If financial assurance is required, submit the documentation required under 12VAC5-481-450 C. NRC NUREG-1757, Vol. 3, 'Consolidated NMSS Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness' dated September 2003 contains acceptable wording for each mechanism authorized by the regulation to guarantee or secure funds. This document is available from the NRC website at: www.nrc.gov or the agency upon request.

Item 9: Facilities and Equipment

Rule: 12VAC5-481-450 A, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-720, 12VAC5-481-780, 12VAC5-481-840, 12VAC5-481-850, 12VAC5-481-860, 12VAC5-481-1200 A, 12VAC5-481-1280, 12VAC5-481-1420, 12VAC5-481-1520

Criteria: Licensees must specifically identify and describe permanent radiographic installations, field stations, and any other locations where radiography will be conducted.

Discussion: A permanent radiographic installation is an enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed. A facility is considered 'permanent' if it is intended to be used for radiography, even if radiography is rarely performed there. The nature of the installation, rather than the frequency of use, determines a permanent radiographic installation. All radiographic operations conducted at locations of use authorized on the license must be conducted in a permanent radiographic installation unless specifically authorized by VDH. If licensees need to perform radiography at their place of business outside of a permanent radiographic installation due to unique circumstances (the item to be radiographed is too large for the facility), then VDH must authorize this method of use. In this case, two individuals must be present whenever radiographic operations occur outside of a permanent radiographic installation.

The one primary (and perhaps the most important) reason licensees have for conducting radiography in a permanent radiographic installation is that they can limit access. In order to ensure this control, a permanent radiographic installation located on the ground, must be enclosed by a minimum of four shielded walls (otherwise the floor must also be shielded). The use of materials, that do not realistically provide shielding, do not qualify. Areas outside of the facility generally should qualify as unrestricted areas. While the area outside of a permanent radiographic installation should qualify as an unrestricted area (i.e., not to exceed 2 mR in one-hour), the rule does not specify radiation limits in order to allow for design flexibility for moving equipment into and out of the permanent radiographic installation, or other considerations. If the roof of the installation does not qualify as a restricted area, or if no roof exists, mechanical access restrictions (fence, etc.) must be utilized and additional administrative controls must be imposed to ensure that unwanted access can be gained only through extraordinary effort. All entrances into the installation must be interlocked with required control devices as per **12VAC5-481-1280**. Unless all entrances are locked, at least one radiographer must be present at the facility whenever radiography is being performed.

A field station is a facility where licensed material may be stored or used and from which equipment is dispatched. Radiographic operations may be conducted in a permanent radiographic installation or at the place of business in the same manner as described above.

A restricted area is an area that licensees limit access for the purpose of protecting individuals from undue risks from exposure to sources of radiation. A restricted area cannot include areas used as residential quarters, consequently industrial radiography devices must not be stored in motel rooms or similar locations.

Requirements for a permanent radiographic installation:

- Each access point is equipped with a visible-audible signal system. The visible signal is activated by radiation whenever the source is exposed. The audible signal will sound if anyone tries to enter the installation while the source is exposed. The

requirement for the visible-audible signal system is in addition to other measures that may be taken to prevent access to the installation, such as locked doors.

As an alternative to the visible-audible alarm system, it is acceptable to use a control system that will reduce the radiation level if the entrance to a high-radiation area is opened while the source is out. The system must be automatic and independent of radiography personnel action. If this alternative is planned, provide a description of the system.

- Diagram depicting the shielding, layout, and audible-visual alarms. A diagram of the installation is helpful in evaluating the shielding and determining compliance with rules regarding restricted and unrestricted areas, location of access points, and locations of audible-visual signals. **Figure 1** shows an example installation diagram.

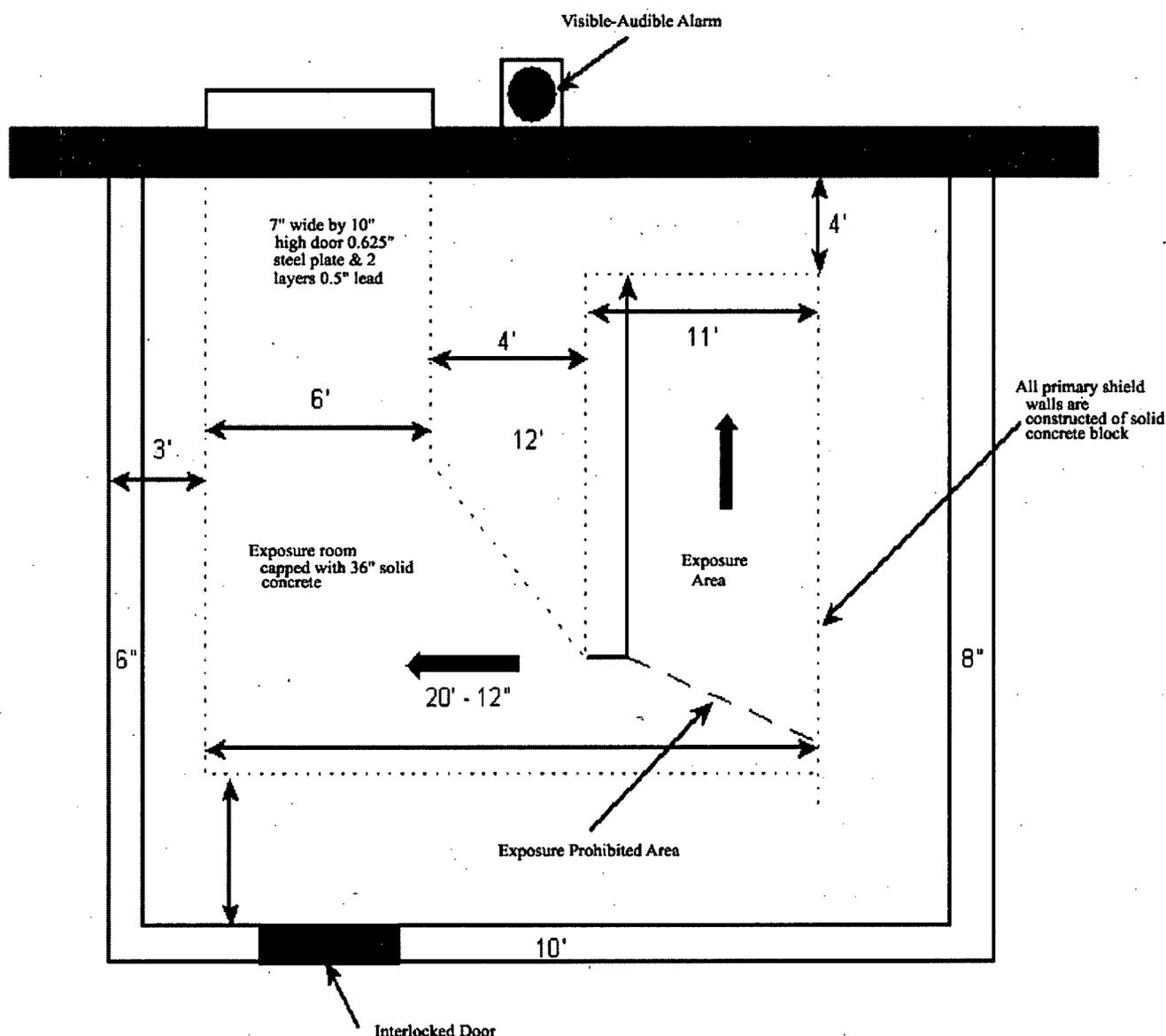


Figure 1: Diagram of a Permanent Radiographic Installation.

- Calculations or survey results of radiation levels: For a determination of installation adequacy, provide information showing that the radiation level in all directions

around the installation, including the roof, will not exceed a dose of 0.02 mSv (2 mrem) in any one hour. Take into account the highest quantity of radioactive material that will be used in the installation and any limitations on source positioning in the installation. Radiation doses in all directions around the installation that are below 0.02 mSv (2 mrem) in any one-hour are considered acceptable. If the radiation doses will exceed 0.02 mSv (2 mrem) in any one-hour, then steps should be taken (use lower-activity source, use collimator, or move setup farther away) to reduce the radiation to the acceptable level.

A radiation level on the roof that exceeds 1.0 mSv (100 mrem) in one hour at 30 cm from the surface is considered a "*High Radiation Area*" and requires special precautions to control access to the area. Licensees should make efforts to lower a radiation level exceeding 1.0 mSv (100 mrem) in any one hour by using additional shielding, collimators, or other engineering controls. The roof of a fixed radiography cell is a potentially occupied area, and applicants must demonstrate that no individual member of the public could receive effective doses in excess of 0.02 mSv (2 mrem) in any one hour or 1 mSv (100 mrem) in a year.

Provide the following as applicable:

- If radiography is planned in a permanent radiography installation or installations (including field stations with permanent exposure cells), provide the following information for each installation:
 - An annotated sketch or drawing of the facility and its surroundings. The scale to which the sketch or drawing is made. The same scale should be used for all sketches and drawings; the recommended scale is 1/4 inch = 1 foot. Drawings to this scale that do not fit on 8 1/2" X 11" paper may be provided as sectional drawings;
 - The type, thickness and density of shielding materials on all sides, including the floor and the roof;
 - The locations of entranceways and other points of access to the facility;
 - A description of the areas adjacent to the facility and the distance to these areas. Include information on areas adjacent to, above, and below the facility;
 - A description of the general location of each proposed permanent installation listed in **Item 4** (e.g., located in an industrial park, an office complex, etc.) and its current use. If any proposed permanent installation is a private residence, provide diagrams of the installation that include the building, the proposed restricted area(s), and adjacent areas, including above and below the restricted areas; provide commitments that restricted areas do not include residential quarters, and explain how radiation levels in unrestricted areas will be maintained at less than 1 mSv (100 mrem) per year;
 - A description of the visible-audible signal system or entrance control system and its location.
 - The results of radiation-level calculations or actual radiation measurements adjacent to, above, and below the installation. The radiation dose in all directions around the installation, including the roof, should not exceed 0.02 mSv (2 mrem) in any one hour. Clearly identify the type of source (isotope), the amount of radioactive material in the source, and the position of the source within the installation for the calculations or measurements.
- Variances will be considered if construction requirements preclude shielding the roof in order to meet the requirement not to exceed 0.02 mSv (2 mrem) in any one hour.

Provide the following information to obtain approval for a variance:

- Procedures for ensuring that no individual is on the roof or could gain access to the roof during radiography;
 - Means of preventing access to the roof;
 - A commitment that the roof will be posted with "*Caution (or Danger) Radiation Area*" signs;
 - Steps taken to minimize radiation on the roof; and
 - Limitations (if needed) on positioning of sources or type (isotope) and amount of radioactive material that may be used in the installation to ensure that areas adjacent to, above, and below the installation will be unrestricted areas during the performance of radiography.
- If radiation doses on the radiography installation roof exceed 1.0 mSv (100 mrem) in any one hour, then provide the following information in addition to the items above to apply for this variance:
 - A commitment that the roof will be posted with "*Caution (or Danger) High Radiation Area*" signs;
 - Evidence of constant surveillance of the roof by closed circuit TV;
 - Fluctuation of the dose rate;
 - A description of a control device that would automatically reduce the radiation level to 1 mSv (100 mrem) in any one hour at 30 cm from the radiation source if someone accesses the roof; and
 - A description of a control device that activates a visible-audible signal so that both an individual accessing the roof and the radiographer on duty are made aware of the entry.
 - Field Stations:
 - Describe the storage location(s) at the address(es) listed in **Item 4** and submit a diagram showing where the radiography camera will be stored at the field stations. Indicate whether or not radiography will be performed at the place of business outside of a permanent radiography installation. If radiography will be performed at a site outside of a permanent radiography installation, provide a diagram of the location where radiography may be performed and its surroundings, including a description of adjacent property;

Response from Applicant:

<p>Item 9 Facilities And Equipment (Check box and attach requested information)</p> <p><input type="checkbox"/> We will submit the required information as listed in the section titled 'Facilities and Equipment' of VAREG 'Guidance for Industrial Radiography Use'.</p>

Note: Certain records described in the rule pertaining to radiation safety may need to be on file at these field stations and each temporary jobsite.

Item 10: Radiation Safety Program

Rule: 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-630, 12VAC5-481-990, 12VAC5-481-1200

Criteria: A radiation protection program must be established and submitted to the agency as part of the application. The program must be commensurate with the scope and extent of activities for the use of licensed materials in industrial radiography. Each applicant for an industrial radiography license must develop, document, and implement a radiation protection program containing the following elements:

- Steps to keep radiation exposures as low as reasonably achievable (ALARA);
- Description of equipment and facilities adequate to protect personnel, the public and the environment;
- Conduct of licensed activities by individuals qualified by training and experience;
- Written operating and emergency procedures;
- Program to inspect the job performance of radiographic personnel ;
- Description of organization structure and individuals responsible for ensuring implementation of radiation safety program; and
- Records management.

Discussion: The specific components of the applicant's radiation safety program are detailed in this guide. Some topics will not require the applicant to submit information as part of an application, but simply provide the applicant with guidance to comply with a specific VDH requirement.

Item 10.1: Radiation Safety Program Audit

Rule: 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-630, 12VAC5-481-990

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

- Compliance with VDH and DOT requirements, and the terms and conditions of the license;
- Occupational doses and doses to members of the public that are ALARA; and
- Records of audits and other reviews of program content are maintained for 3 years.

Discussion: **Appendix I** contains a suggested annual audit program that is specific to industrial radiography and is acceptable to the agency. All areas indicated in **Appendix I** may not be applicable to every licensee and may not need to be addressed during each audit.

Audit records acceptable to the agency should contain the following information:

- Date of audit;
- Name of person(s) who conducted the audit;
- Names of persons contacted by the auditor(s);
- Areas audited;
- Audit findings, and corrective actions; and
- Follow-up.

It is essential that once identified, problems be corrected 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.

Response from Applicant:

Item 10.1 Radiation Safety Program Audit

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

Item 10.2: Termination of Activities

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-490, 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 F**;
- 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 D**. If licensed activities are transferred or assigned in accordance with **12VAC5-481-500 B**, transfer records important to decommissioning to the new licensee.

Discussion: For guidance on the disposition of radioactive material, see **Item 11** 'Waste Management'. For guidance on decommissioning records, see **Item 8** 'Financial Assurance and Record Keeping for Decommissioning'.

Response from Applicant:

<p>Item 10.2 Termination Of Activities (Check box)</p> <p><input type="checkbox"/> We will notify the agency, in writing, within 30 days of the decision to permanently cease radioactive material use. (12VAC5-481-500)</p>
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Item 10.3: Instruments

Rule: 12VAC5-481-450 A, 12VAC5-481-490 B, 12VAC5-481-750, 12VAC5-481-1000, 12VAC5-481-1240, 12VAC5-481-1260, 12VAC5-481-1270, 12VAC5-481-1330, 12VAC5-481-1410

Criteria: A radiation survey meter intended for industrial radiography that utilizes sealed radioisotope sources should be capable of accurately measuring the radiation fields produced by the sealed radiography source currently in use, and be visually checked for damage and for proper operation with a check source or other appropriate means, such as an exposure device, before use on each day it is to be used. The survey meter shall be calibrated at intervals not to exceed 6 months and after each servicing (except for battery changes). Written procedures are required for inspection and routine maintenance of the survey meters, which is to be performed at intervals not to exceed 3 months or before the first use thereafter to ensure proper functioning of components.

Discussion: The licensee shall keep an adequate number of appropriate radiation survey instruments that are both calibrated and operable, at each location where radioactive material is present to make the required radiation surveys. The instrument shall be capable of measuring a range from 0.02 mSv (2 mrem) per hour through 10 mSv (1 rem) per hour. Each radiation survey instrument shall be calibrated at intervals not to exceed 6 months and after instrument servicing, except for battery changes. Records of survey instrument calibrations will be retained for a minimum of 3 years. Records are to be made of equipment problems and maintenance performed and these shall be retained for 3 years.

Response from Applicant:

<p>Item 10.3 Instruments (Check all boxes that apply)</p> <p><input type="checkbox"/> We will possess and use radiation survey meter(s) that meets the Criteria in the section titled 'Instruments' in VAREG 'Guidance for Industrial Radiography Use'.</p> <p style="text-align: center;">AND EITHER</p> <p><input type="checkbox"/> The calibration will be performed by a VDH, NRC or another Agreement State licensee specifically authorized to perform instrument calibration.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will follow the survey meter calibration procedures in accordance with Appendix J in VAREG 'Guidance for Industrial Radiography Use'.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will submit alternate procedures. (Procedures are attached)</p> <p>Note: Identify the qualifications of the individuals who will perform the calibrations if performed by the applicant.</p>
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Note: For detailed information about survey instrument calibration, refer to ANSI N323-1978, 'Radiation Protection Instrumentation Test and Calibration'. Reaffirmed 1993 copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018.

Item 10.4: Material Receipt and Accountability

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-840, 12VAC5-481-900, 12VAC5-481-980, 12VAC5-481-1090, 12VAC5-481-1260, 12VAC5-481-1400, 12VAC5-481-3091, 12VAC5-481-3100

Criteria: Licensees must do the following:

- Maintain records of receipt, transfer, and disposal of sources/devices; and
- Conduct physical inventories at quarterly intervals (not to exceed 3 months) to account for all sources of radiation and for devices, including devices containing depleted uranium;

Discussion: Licensed materials must be tracked from 'cradle to grave' in order to ensure accountability; identify when sources/devices may be lost, stolen, or misplaced; and ensure that the possession limit stated on the license is not exceeded.

Conduct physical inventories (i.e., locate, verify the presence of the material, and account for it in material transfer record) at quarterly intervals (not to exceed 3 months) to account for all sealed sources and devices containing depleted uranium.

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.

'Cradle to Grave' accountability refers to maintaining the radioactive material from the moment it becomes a part of your organization 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).

Response from Applicant:

Item 10.4 Material Receipt And Accountability (Check box)

- Quarterly physical inventories (not to exceed 3 months) will be conducted of all sealed sources and/or devices containing radioactive material (including depleted uranium) and the information contained in the discussion section titled 'Material Receipt and Accountability' in VAREG 'Guidance for Industrial Radiography Use' will be documented.

Item 10.5: Leak Tests

Rule: 12VAC5-481-180, 12VAC5-481-740, 12VAC5-481-1010, 12VAC5-481-1150, 12VAC5-481-1200, 12VAC5-481-1250, 12VAC5-481-1420

Criteria: VDH requires testing to determine whether there is any radioactive leakage from the source or from devices containing depleted uranium shielding. The agency finds testing to be acceptable if it is conducted by an organization licensed by VDH, NRC, or another Agreement State, or conducted in accordance with procedures approved by the agency.

Discussion: Manufacturers, consultants, and other organizations may be authorized by VDH, the NRC or another Agreement State to either perform the entire leak test sequence for other licensees or provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample according to the device manufacturer's and the kit supplier's instructions and return it to the kit supplier for evaluation and reporting results. Licensees may also be authorized by VDH to conduct the entire leak test sequence themselves. Measurement of the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 microcurie) of radioactivity.

Sealed sources containing radioactive material must be leak tested at intervals not to exceed 6 months and DU devices tested at intervals not to exceed 12 months.

Response from Applicant:

<p>Item 10.5 Leak Tests (Check one box)</p> <p><input type="checkbox"/> Leak tests will be performed by an organization authorized by VDH, the NRC or another Agreement State to provide leak testing services to other licensees; or by using a leak test kit supplied by an organization licensed by VDH, the NRC or another Agreement State to provide leak test kits to other licensees according to kit suppliers' instructions.</p> <p>List the name and license number of organization authorized to perform or analyze leak tests (Specify whether VDH, NRC, or another Agreement State):</p> <p>Organization Name _____ License Number _____</p> <p>Issuing Entity _____</p> <p>Note: An alternate organization may be used to perform or analyze leak tests, without amending the license, provided the organization is specifically authorized by VDH, the NRC or another Agreement State.</p> <p>OR</p> <p><input type="checkbox"/> We will perform our own leak testing and sample analysis. We will follow the procedures in Appendix K of VAREG 'Guidance for Industrial Radiography Use'.</p> <p>OR</p> <p><input type="checkbox"/> We will submit alternative procedures. (Procedures are attached)</p>
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Note: Requests for authorization to perform leak testing and sample analysis will be reviewed on a case-by-case basis and, if approved, VDH staff will authorize via a license condition.

Item 10.6: Occupational Dosimetry

Rule: 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-690, 12VAC5-481-700, 12VAC5-481-710, 12VAC5-481-750, 12VAC5-481-760, 12VAC5-481-770, 12VAC5-481-1030, 12VAC5-481-1040, 12VAC5-481-1350, 12VAC5-481-2280

Criteria: Licensees must provide to employees dosimetry processing that has been accredited under the National Voluntary Laboratory Accreditation Program (NVLAP) operated by the National Institute of Standards and Technology (NIST).

Table 7: Occupational Dose Limits For Adults

Occupational Dose Limits for Adults (12VAC5-481-640)	
<u>Body Location</u>	<u>Dose (Annual)</u>
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)
<i>*Extremities includes the arms below the elbows and the legs below the knees</i>	

Discussion: The licensee may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations each individual wears, on the trunk of the body, a combination of a direct-reading dosimeter (pocket dosimeter or electronic personal dosimeter), an operating alarm ratemeter, and either a film badge or optical stimulated lamination (OSL) or similar approved device. At permanent radiography installations where other appropriate alarming or warning devices are in routine use, wearing an alarming ratemeter is not required. The pocket dosimeters must have a range from zero to 2 mSv (200 mrem), must be recharged at the start of each shift, and must be checked for correct response to radiation at intervals not to exceed 12 months. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters. Alarming ratemeters must be preset to give an alarm signal at a dose rate of 5 Sv/hr (500 mrem/hr) and must be calibrated for correct response at intervals not to exceed 12 months.

Film badges, OSLs or similar approved devices must be replaced at frequencies not to exceed 1 month.

Response from Applicant:

<p>Item 10.6 Occupational Dosimetry (Check all boxes that apply)</p> <p><input type="checkbox"/> We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged monthly.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> The required personnel monitoring equipment, including 0 to 2 mSv (200 mrem) dosimeters or electronic personal dosimeters, will be worn by radiographic personnel.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Alarming ratemeters set to alarm at plus or minus 20% of 500 mrem/hour will be worn by all radiography personnel.</p> <p>Note: Radiography personnel at permanent radiography installations where other appropriate alarming or warning devices are in use do not need alarming ratemeters.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Pocket dosimeters and alarm ratemeters will be checked for correct response at intervals not to exceed 12 months.</p> <p style="text-align: center;">AND EITHER</p> <p><input type="checkbox"/> If adjustment is necessary, the devices will be returned to the manufacturer.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> If adjustment is necessary, procedures for adjustments are described.</p>

Note: To obtain a copy of the NIST Publication 810, 'National Voluntary Laboratory Accreditation Program, 1997 Directory', contact the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9225. (For information on the program call NIST at 301-975-3679). Also NVLAP maintains a directory of accredited laboratories on the Internet which is updated quarterly. The URL for NVLAP's home page on the internet is <http://ts.nist.gov/nvlap>.

Item 10.7: Public Dose

Rule: 12VAC5-481-630, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-840, 12VAC5-481-1050, 12VAC5-481-1230, 12VAC5-481-1280, 12VAC5-481-1330, 12VAC5-481-1370, 12VAC5-481-3080

Criteria: Licensees must do the following:

- Ensure that radiography devices will be used, transported, and stored in such a way that members of the public will not receive more than 1 mSv (100 mrem) in a year, and the dose from licensed operations in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour; and
- Control and maintain constant surveillance over devices that are not in storage and secure stored devices from unauthorized removal or use.

Discussion: Operating and emergency procedures that address security and surveillance should be sufficient to limit exposure of the public during use and after accidents. Public dose is controlled, in part, by ensuring that devices not in use are stored securely (e.g., stored in a locked area) to prevent unauthorized access or use. If devices are not in storage, then authorized users must maintain constant surveillance.

Public dose is also affected by the choice of the permanent radiographic installation and storage locations and conditions. An example of a properly stored device would be a locked room a sufficient distance from any individual, especially personnel. Use of area monitors such as an OSL is an acceptable means of demonstrating compliance with the annual limit of 1 mSv (100 mrem) in unrestricted areas.

Use the concepts of time, distance, and shielding when choosing a permanent radiographic installation or storage location. Decreasing the time spent near radiographic operations, increasing the distance of the device from occupied locations, using shielding material (i.e., high density concrete, solid block, or lead sheets), and implementing conservative operating procedures (i.e., use of collimators or limiting the direction of exposures towards the floor) will reduce the radiation exposure of personnel and members of the public. Alternatively, the remote location of and access to a permanent radiographic installation could prevent members of the public from receiving 1 mSv (100 mrem) in a year.

If, after an initial evaluation, a licensee makes changes affecting the permanent radiographic installation storage area (e.g., changing the location of devices within the storage area, removing shielding, adding devices, changing the occupancy of adjacent areas, moving the storage area to a new location), then the licensee must perform a new evaluation to ensure that the public dose limits are not exceeded and devices are properly secured.

Response from Applicant:

Item 10.7 Public Dose

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

Note: Appendix L provides additional information for determining that radiation doses for other licensee personnel and members of the public will not be exceed allowable limits.

Item 10.8: Quarterly Maintenance

Rule: 12VAC5-481-630, 12VAC5-481-1210, 12VAC5-481-1260, 12VAC5-481-1270, 12VAC5-481-1290, 12VAC5-481-1330, 12VAC5-481-1430, 12VAC5-481-1450, 12VAC5-481-3130

Criteria: The licensee shall have written procedures for inspecting and maintaining radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments. Inspection and maintenance must be conducted at intervals not to exceed every 3 months, or before the first use thereafter, to ensure the proper functioning of components important to safety. The licensee must also have procedures necessary to maintain the Type B packaging used to transport radioactive materials, ensure that Type B packages are shipped properly, and maintain Type B packages in accordance with the Certificate of Compliance (COC) issued by NRC or other agencies approving such transport packages.

If equipment problems are found, the equipment must be withdrawn from service until repaired, records are required.

Discussion: These procedures are intended to allow the licensee's staff to evaluate equipment used in radiography for safe continued use, to provide a record of this evaluation, and to guide the staff in maintenance. Equipment found to be unsuitable for service must be withdrawn until repair and an evaluation for return to service is made. These procedures may be based on the manufacturer's recommendations. The procedures are to be specific to the equipment. For example, radiography drive cable assemblies should be cleaned and lubricated (when operationally appropriate) in accordance with the recommendations of the equipment manufacturer or the cable manufacturer or alternatively, with any lubrication and cleaning recommendations established by the industrial radiography community.

Procedures are also required for Type B packaging used to transport radioactive materials. These procedures are to be used for shipping and maintenance, and may be properly drawn from the manufacturer's procedures and information submitted as a basis for the COC or other transport package approval.

Response from Applicant:

Item 10.8 Quarterly Maintenance (Check both boxes)

We have included procedures for quarterly maintenance as part of the operating and emergency procedures.

AND

Before using a new sealed source/device combination, we will have written inspection and maintenance procedures that address the use of new equipment as a Type B transport package. In addition, we will provide training to radiographic personnel before using a new sealed source/device combination.

Operating and Emergency Procedures

Item 10.9: Operating and Emergency Procedures

Rule: 12VAC5-481-450, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-860, 12VAC5-481-880, 12VAC5-481-900, 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1200, 12VAC5-481-1330, 12VAC5-481-1480, 12VAC5-481-1520, 12VAC5-481-2260

Criteria: Operating and emergency procedures must be established and submitted to the agency as part of the application package. In addition, if radiographers will perform other operations such as source exchange, leak-testing, and quarterly (not to exceed 3 months) inspection and maintenance of equipment, appropriate procedures and instructions for these operations should be included in the operating and emergency procedures.

Each licensee must develop, implement, and maintain operating and emergency procedures containing the following elements:

- Instructions for maintaining security during storage and transportation;
- Instructions to keep radiography devices under control and immediate surveillance during use;
- Steps to take to keep radiation exposures ALARA;
- Steps to maintain accountability during use;
- Steps to control access to work sites;
- Use of personnel monitoring and radiation survey equipment;
- Instruction for packaging and transporting licensed material; and
- Steps to take and whom to contact when an emergency occurs.

Discussion: The purpose of operating and emergency procedures is to provide radiography personnel with specific guidance for all operations they will perform. These topics should be included in the operating and emergency procedures and need not be presented in order of importance. A sequential set of procedures and instructions from the beginning to the end of the workday is an acceptable format. Instructions for non-routine operations, for example, quarterly (not to exceed 3 months) inspection and maintenance or instrument calibration, may be included as separate appendices.

It is not necessary for operating and emergency procedures to be specific to a particular make and model of exposure device, source exchanger, or survey instrument. Procedures submitted to the agency should provide sufficient guidance and instruction for each specific type of device. For example, you may submit a single operating procedure for crank-out regardless of the manufacturer and/or a single operating procedure for pipeliner exposure devices regardless of manufacturer.

Applicants who plan to conduct lay-barge, offshore platform, or underwater radiography are required to have their procedures approved by the agency. If you plan to conduct lay-barge, offshore platform or underwater radiography, your radiation safety program will be reviewed to assure that it contains procedures that specifically address:

- Transport of licensed material;
- Storage facilities for licensed material;
- Methods for restricting access to radiation areas;
- Radiation safety procedures and radiographer responsibilities unique to lay-barge, offshore platform, or underwater radiography;
- Radiographic equipment and radiation safety procedures unique to underwater radiography;
- Methods appropriate for use of equipment in water environments;
- Applicable inspection and maintenance procedures unique to lay-barge, offshore platform, or underwater radiography equipment; and
- Emergency procedures unique to lay-barge, offshore platform, or underwater radiography.

Operating and emergency procedures must be submitted to the agency for review.

Note that providing specific operating and emergency procedures for a particular manufacturer's make and model number will require an amendment to the license to obtain VDH's authorization for a new sealed source/device combination.

Response from Applicant:

Item 10.9 Operating and Emergency Procedures

Operating and emergency procedures must be submitted to the agency for review.
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Item 10.9.1: Handling and Use of Sealed Sources and Radiography Exposure Devices

Rule: 12VAC5-481-1210 C, 12VAC5-481-1330

Criteria: Licensees need to establish operating and emergency procedures.

Discussion: There are two types of devices normally used for radiography, crankout, and pipeliner. There should be separate instructions for each type of device. Separate instructions are not necessary for each different model of a given type of device since the operation of each type is essentially the same regardless of the manufacturer. Some applicants may choose to use one basic instruction for all crankout devices; others may choose to have separate instructions for each model. Either approach is acceptable.

Specific procedures should be required for performing source exchanges, including those at temporary jobsites, field stations, and in a permanent radiographic installation. The procedures should contain warnings of areas of concern during source exchanges. Recent incidents of sources becoming dislodged from the shielded position indicate the importance of training personnel in the appropriate techniques. Procedures should require the use of survey instruments, dosimetry, and surveys during and after movement of sources.

Response from Applicant:

Item 10.9.1 Handling And Use Of Sealed Sources And Radiography Exposure Devices (Check box)

- We have included the following in the operating and emergency procedures:
Step-by-step instructions for using each type of radiographic devices;
Instructions for performing source exchanges; and
Instructions for crankout devices should be separate from those for pipeliner devices.

Note: Manufacturers' manuals and similar documents should not be incorporated into the procedures, rather, information should be extracted from them and paraphrased.

Appendix M provides information for applicants to consider when developing their procedures for operating radiography equipment.

Item 10.9.2: Methods and Occasions for Conducting Radiation Surveys

Rule: 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-900, 12VAC5-481-1210, 12VAC5-481-1220, 12VAC5-481-1240, 12VAC5-481-1250, 12VAC5-481-1360, 12VAC5-481-2980, 12VAC5-481-3080

Criteria: Perform radiation surveys during use, movement, and storage of licensed material to ensure its safe use and comply with regulatory requirements.

Discussion: In general, surveys need to be made whenever a source is manipulated or moved. Surveys should be made with a radiation survey instrument calibrated in accordance with **12VAC5-481-1240**. The following table provides examples of surveys, made during radiographic and associated operations that should be included in the operating and emergency procedures.

Table 8: Surveys Required for Radiographic Operations

Type of Radiation Survey	Frequency	Requirement
Boundary of restricted area at temporary jobsite does not exceed 0.02 mSv (2 mrem) in any one hour	During the first exposure for each set up of radiographic device	12VAC5-481-720
Unrestricted area in vicinity of permanent radiographic installation or storage area does not exceed 1 mSv (100 mrem) per year	At intervals not to exceed 12 months	12VAC5-481-730
External radiation levels when a package is received and opened	Each receipt of package	12VAC5-481-900
Exposure rate does not exceed 2 mSv/hr (200 mrem/hr) on surface and 0.1 mSv/hr (10 mrem/hr) at one meter	Each installation of new source in exposure device	12VAC5-481-1210 A
Exposure rate does not exceed 2 millisieverts (200 millirem) per hour at any exterior surface, and 0.1 millisieverts (10 millirem) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.	Each installation of new source in a storage container or source changer	12VAC5-481-1220
Contamination level for leak tests of sealed sources does not exceed 185 Bq (0.005 microcuries)	At intervals not to exceed 6 months	12VAC5-481-1250 C
Contamination level for leak test of S tube of exposures device does not exceed 185 Bq (0.005 microcuries)	At intervals not to exceed 12 months	12VAC5-481-1250 E
Confirm source has returned to a shielded position	After every radiographic exposure	12VAC5-481-1360 2
Confirm source is in shielded position	After every source exchange or exposure device is placed in storage	12VAC5-481-1360 3
Exposure rates meet labeling of package (i.e., Yellow II) and determine Transportation Index	Every movement of licensed material on public roads	12VAC5-481-2980 A
Exposure rates in and around vehicle do not exceed 0.002 mSv/hr (2 mrem/hr) in driver's seat, 2 mSv/hr (200 mrem/hr) on surface and 0.1 mSv/hr (10 mrem/hr) at 2 meters from vehicle	Every movement of a package labeled Yellow III	12VAC5-481-3080

Response from Applicant:

<p>Item 10.9.2 Methods And Occasions For Conducting Radiation Surveys (Check box)</p> <p><input type="checkbox"/> We have included in the operating and emergency procedures all surveys as described in the section titled 'Methods And Occasions For Conducting Radiation Surveys' in VAREG 'Guidance for Industrial Radiography Use'.</p>

Item 10.9.3: Methods for Controlling Access to Radiographic Areas

Rule: 12VAC5-481-780, 12VAC5-481-840, 12VAC5-481-860, 12VAC5-481-1230, 12VAC5-481-1280, 12VAC5-481-1290, 12VAC5-481-1300, 12VAC5-481-1330, 12VAC5-481-1370, 12VAC5-481-1380, 12VAC5-481-1460, 12VAC5-481-1500

Criteria: Each licensee must control access to areas where licensed material is either used or stored to prevent the unnecessary exposure of members of the public. This can be achieved through the use of posting, by locking devices and areas where licensed materials are stored, and by maintaining constant control and continuous surveillance of areas where radiographic operations are conducted. Operating and emergency procedures should include steps for radiographic personnel to ensure that access to licensed materials is controlled for the types of operations that will be performed.

Discussion:

1. Field/Temporary Jobsites

When radiographic operations are performed outside a permanent radiographic installation, at least two qualified radiographic personnel must be present. At least one of the individuals must be a radiographer; the other may be another radiographer or a radiographer's assistant. Both individuals must maintain constant surveillance of the operations to prevent unauthorized entry to the restricted area. Operating procedures must comply with the two-man rule for radiographic operations at any locations other than permanent radiographic facilities.

Radiographic personnel are required to maintain continuous direct visual surveillance of operations to protect against unauthorized entry to the high radiation area during radiographic operations. Radiographic personnel should be instructed to keep the perimeter of the restricted area under continuous surveillance to prevent unnecessary exposure of individuals. Operating procedures should specify steps for responding to unauthorized entry to the restricted area. For example, personnel should be instructed to terminate the radiographic exposure immediately, before confronting the person who entered the restricted area.

All areas where radiographic operations are conducted require posting of the radiation areas and the high radiation areas. It is acceptable to post the perimeter of the restricted area rather than the perimeter of the radiation area. Personnel should be instructed to post "*Caution Radiation Area*" signs at the point where radiation levels have been calculated to reach 0.02 mSv (2 mrem) in any one hour. A confirming survey during the first exposure of the source should be conducted to confirm the location of the boundary and any necessary adjustments should be made.

The perimeter of the high radiation area must be posted with a "*Caution (or Danger) High Radiation Area*" sign(s) at the point where radiation levels have been calculated to reach 1 mSv (100 mrem) in any one hour. A confirming survey of the high radiation area perimeter should not be conducted, since such a survey could lead to unnecessary exposure of personnel.

Surveillance of the restricted area at facilities with multiple levels and multiple access points, or where members of the public are close to the radiographic operations (e.g., boilers, commercial manufacturing plants, or power plants during outages) can usually be performed only when more than two radiographic personnel are assigned to the job. Operating procedures and instruction to personnel should include specific steps for these circumstances to ensure that access into the restricted area is properly controlled. Adequate control of the restricted area at with multiple

levels would require several personnel and many postings. These special instructions may include the use of additional personnel to assist radiographic personnel in controlling access into the restricted area, providing instruction to other workers in the area, or making announcements over the public address system before and during radiographic operations.

2. Permanent Radiographic Installations

For permanent radiographic installations, instruct personnel about posting each entrance to the facility with a "*Caution (or Danger) High Radiation Area*" sign(s), and provide procedures to ensure that the visible-audible signal system is operable. The operability of the visible-audible system must be checked daily. The following procedures may be used:

- Expose a radiation source in the permanent installation with all entrances closed;
- Determine that each visible signal in and outside the installation is functional;
- Open the door to each entrance into the installation to activate the audible alarm;
- Close the entrance and confirm that the alarm stops. If the installation has more than one entrance, only one entrance should be tested at a time; and
- Record results of test.

In the event that an entrance control device or an alarm fails to operate properly at the permanent radiographic installation, the installation may continue to operate for up to 7 days while the defective equipment is fixed, provided that:

- The entrance control device is labeled as defective;
- Radiography personnel maintain continuous, direct, visual surveillance of access installation points; and
- Radiography personnel use an alarming rate meter.

3. Storage Areas

Radiographic equipment containing licensed material stored in controlled or unrestricted areas must be secured from unauthorized removal or access. Operating procedures should specify how stored licensed material should be secured and who is authorized access to licensed material.

A vehicle used to transport licensed material can also be used for storage at locations such as temporary jobsites or overnight lodging. If the applicant plans to use vehicles for storage, there should be procedures and instructions to personnel about proper posting of the vehicle. A physical survey should be performed to confirm that the area around the storage facility is an unrestricted area. Radiation levels may not exceed 0.02 mSv/hr (2 mrem/hr) at 45 cm (18 inches) from any external surface of the vehicle and the vehicle shall be locked when it is used for storage.

Radiographic equipment stored at temporary jobsites must be secured at a location that prevents access by unauthorized personnel. This usually requires that the equipment be locked in a cabinet or other secure area where key access is controlled by site management and radiographic personnel. It is not acceptable for a device to be chained to a post and left unattended at the place of use during lunch, breaks, or after hours. Storage of exposure devices at a private residence is unacceptable unless it has been identified and approved in a license.

Response from Applicant:

Item 10.9.3 Methods For Controlling Access To Radiographic Areas (Check box)

- We have included procedures to control access to radiographic operations and storage areas in the operating and emergency procedures

Note: All regulatory criteria applying to your normal place of business for conducting industrial radiography operations also apply to the location in which you store at your private residence. You must specify this storage location in your license application.

Item 10.9.4: Methods And Occasions For Locking And Securing Radiographic Exposure Devices, Storage Containers, and Sealed Sources

Rule: 12VAC5-481-840, 12VAC5-481-1210, 12VAC5-481-1230, 12VAC5-481-1360

Criteria: 12VAC5-481-840 and 12VAC5-481-1230 requires locking and securing radiographic equipment to protect the public and radiographers from an inadvertent exposure to radiation.

Discussion: All radiographic devices, i.e., gamma cameras, sealed source storage containers, and source changers are required to have a lock or outer-locked container to maintain the sealed source in its shielded position. During radiographic operations the source must automatically be secured in the shielded position each time the source is returned. Radiographers must not attempt to circumvent the automatic securing features or tamper with the safety features of radiographic devices. If a radiographer had to leave an exposure device at a temporary jobsite, it would have to be secured against unauthorized removal or tampering by using the lock on the device and then locking it in an available space such as a shed, room, etc. Likewise, while in storage to and from the temporary jobsite, the radiographer would ensure the lock is on the device and then lock the device in the trailer, etc. Radiographers and/or radiographer's assistants must ensure that the exposure device and/or storage or source containers are maintained locked (and if key locked, with the key removed at all times) when they are not under the direct supervision of the radiographer or the radiographer's assistant, except at permanent radiographic installations.

Response from Applicant:

Item 10.9.4 Methods and Occasions For Locking and Securing Radiographic Exposure Devices, Storage Containers, and Sealed Sources (Check box)

- We have included procedures for locking and securing radiographic equipment in the operating and emergency procedures

10.9.5: Personnel Monitoring and the Use of Personnel Monitoring Equipment

Rule: 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-710, 12VAC5-481-750, 12VAC5-481-760, 12VAC5-481-770, 12VAC5-481-1040, 12VAC5-481-1330, 12VAC5-481-1350, 12VAC5-481-1490, 12VAC5-481-2280

Criteria: Provide procedures for appropriate use of personnel monitoring equipment.

Discussion: All radiographers or radiographer's assistants are required to wear on the trunk of their body:

- Direct-reading dosimeters;
- Film badges, OSLs or similar devices; and
- Alarm ratemeters when they are engaged in radiographic field operations.

Film badges, OSLs or similar devices must be assigned to and worn by only one individual. To ensure full-scale reading capability, direct reading dosimeters such as pencil (pocket) dosimeters or electronic personal dosimeters must be recharged or reset at the start of each shift so that the dosimeters will be capable of reading the full scale. Personnel should be instructed that direct reading dosimeters must be read and recorded at the beginning and end of each shift. Proper

operation of alarm ratemeters must be checked each day before use to ensure that the alarm functions properly. The manufacturer's recommended procedures should be followed.

All radiographers or radiographer's assistants are required to wear alarm ratemeters except at permanent radiographic facilities where other appropriate alarm or warning devices (e.g., visible and audible alarms) are in routine use and are operable.

Include instructions about how and where dosimetry devices are to be stored when not in use. The storage place should be dry, radiation free, and cool so that the devices will not be affected by adverse environmental conditions.

Response from Applicant:

<p>Item 10.9.5 Personnel Monitoring And The Use Of Personnel Monitoring Equipment (Check box)</p> <p><input type="checkbox"/> We have included instructions for proper use of personnel monitoring equipment in the operating and emergency procedures</p>

Note: It is good practice to check the dosimeter during the work shift.

Item 10.9.6: Transporting Sealed Sources To Field Locations, Securing Exposure Devices And Storage Containers In Vehicles, Posting Vehicles, And Controlling Sealed Sources During Transportation

Rule: 12VAC5-481-630, 12VAC5-481-1210, 12VAC5-481-2980, 12VAC5-481-3070, 12VAC5-481-3080, 12VAC5-481-3091, 12VAC5-481-3100, 12VAC5-481-3130, 49 CFR Parts 171-178

Criteria: Licensees must develop, implement, and maintain procedures for transporting radioactive material to ensure compliance with DOT regulations.

Discussion: During an inspection, the agency uses the provisions of 12VAC5-481-2980 which incorporates the requirements of 49 CFR, to examine and enforce transportation requirements applicable to radiography licensees. **Appendix N** contains: 1) a list of major DOT regulations applicable to transporting radiographic devices; 2) a condensed summary of VDH/DOT requirements; and 3) two sample shipping papers, the second of which may be more useful for multiple-use, temporary jobsite activities.

Instructions to personnel should not reference VDH/DOT requirements. Information should be extracted, paraphrased and placed into the instructions so that personnel know exactly what they are expected to do. The following items should be covered in instructions to personnel:

- Labeling containers appropriately (i.e., when to use labels Radioactive White I, Radioactive Yellow II, or Radioactive Yellow III);
- Securing the exposure device or storage container within the transporting vehicle. The instructions should specify how to prevent the package from moving during transport;
- Preparation of shipping papers. The instructions should specify that the papers must be completed before transporting the licensed material and must be accessible in the driver's compartment at all times. **Appendix N** contains examples of shipping papers for transporting radiographic exposure devices;

- Placarding both sides, the front, and the back of the vehicle with "*RADIOACTIVE*" placards if the package being transported requires a Radioactive Yellow III label. If the vehicle requires placarding and the package radiation levels exceed 2 mSv/hr (200 mrem/hr) or the transport index exceeds 10, exterior surfaces and passenger compartment of the vehicle must be surveyed to ensure that the radiation levels do not exceed 0.02 mSv/hr (2 mrem/hr) from any exterior surface and 0.02 mSv/hr (2 mrem/hr) in the passenger compartment. Include instructions to personnel on the measures to take if the radiation level exceeds 0.02 mSv/hr (2 mrem/hr) in the passenger compartment (e.g., adding more shielding or repositioning the device within the vehicle);
- Ensure that the licensee's name and city/town is prominently displayed as a label on both sides of the vehicle; and
- If an exposure device is transported in an overpack, the procedures should include instructions that the overpack must be properly marked with the shipping name and identification number, labeled (Radioactive White I or Radioactive Yellow II), and marked when required with a statement that indicates the inner package complies with prescribed specifications.

Because the licensee may have authorization to possess and use several sealed source/device combinations that are registered by the NRC or another Agreement State and meet the safety performance requirements of **12VAC5-481-1210**, the applicant must, before using a new sealed source/device combination, develop written inspection and maintenance procedures for it and for the corresponding Type B transport package. In addition, the applicant must provide adequate training for radiographic personnel before using a new sealed source/device combination.

Response from Applicant

<p>Item 10.9.6 Transporting Sealed Sources To Field Locations, Securing Exposure Devices And Storage Containers In Vehicles, Posting Vehicles, And Controlling Sealed Sources During Transportation (Check one box)</p> <p><input type="checkbox"/> We have included procedures for transporting sealed sources containing radioactive material, exposure devices, and source changers in the operating and emergency procedures.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> Not Applicable (Devices are not transported)</p>

Note: 'A Review of Department of Transportation Regulations for Transportation of Radioactive Materials (1998 revision)' can be obtained by calling DOT's Office of Hazardous Material Initiatives and Training at (800) 467-4922.

Before the 1997 revision of **10 CFR Part 34**, a licensee who intended to transport a radiographic Type B package was required to submit a quality assurance program to NRC for approval, separate from the license approval. The 1997 revision to **10 CFR Part 34** requires written procedures for inspection and maintenance of radiographic Type B packages (**10 CFR 34.31(b)**). In conjunction with the revision to **10 CFR Part 34**, the NRC also amended **10 CFR 71.101(g)** to specifically state that if the applicant's written procedures for inspection and maintenance of radiographic Type B packages are approved, then the applicant also meets NRC quality assurance requirements in **10 CFR Part 71** and does not have to submit or maintain a separate quality assurance program to transport a Type B package. The application's inspection and maintenance procedures for radiographic equipment, which are also used for Type B packages, should ensure that these packages are shipped and maintained in accordance with their COC.

Item 10.9.7: Daily Inspection and Maintenance of Radiography Equipment

Rule: 12VAC5-481-1210, 12VAC5-481-1240, 12VAC5-481-1260, 12VAC5-481-1270, 12VAC5-481-1280 B, 12VAC5-481-1290, 12VAC5-481-1330, 12VAC5-481-1350, 12VAC5-481-1360, 12VAC5-481-1410, 12VAC5-481-1430, 12VAC5-481-1450, 12VAC5-481-1460, 12VAC5-481-1490

Criteria: The licensee shall perform visual and operability checks before using radiography equipment on each day it is used.

Discussion: Visual and operability checks must be performed on radiographic exposure devices, survey meters, associated equipment, and transport and storage containers before use each day the equipment is used. These checks are intended to ensure that the equipment is in good working condition, the sources are adequately shielded, and required labeling is present. Licensees must check survey instrument operability using check sources or other appropriate means.

Inspection records shall contain information about equipment problems found in daily checks and quarterly (not to exceed 3 months) maintenance inspections. Records shall include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was done.

Instructions to personnel using radiographic equipment must clearly state that inspections are to be made before the equipment is used each day. While not a requirement, good practice would be that if the equipment is used on more than one shift in the day, the equipment should be inspected before the start of each shift.

The procedures should specify the items that are to be checked and the steps that are to be taken if any defects are found. If problems are found, the equipment must be removed from service until it is repaired.

A list of items that should be checked in the daily inspection of radiography equipment can be obtained by contacting the equipment manufacturers.

Permanent radiographic installation visible and audible alarms must be checked for operability daily before use, and faulty radiographic equipment must be labeled and repaired within 7 days, with compensatory measures taken in the interim. Compensatory measures taken include:

- Immediately label faulty equipment as defective;
- The radiographer must be accompanied by at least one other radiographer or radiographer's assistant;
- Continuous surveillance requirements are implemented until repairs are completed;
- Alarming ratemeters shall be worn and checked for alarm function at the beginning of each shift; and
- Records must be maintained of faulty equipment.

Appendix O provides example instructions for daily inspection of radiographic devices and equipment.

Response from Applicant:

Item 10.9.7 Daily Inspection And Maintenance Of Radiography Equipment (Check box)

- We have included procedures for daily inspection and maintenance of radiography equipment in our operating and emergency procedures.

Note: Direct reading dosimetry devices must be read and the exposures recorded at the beginning and end of each shift. Alarm ratemeters shall be checked for alarm function at the beginning of each shift. Records are to be maintained per 12VAC5-481-1490.

Item 10.9.8: Ratemeter Alarms or Off-Scale Dosimeter Readings

Rule: 12VAC5-481-1320, 12VAC5-481-1330, 12VAC5-481-1350 D

Criteria: Licensees must instruct personnel in:

- Appropriate handling and use of sealed radioisotope sources and radiography devices;
- Methods and occasions for conducting radiation surveys, controlling access to radiation areas and locking, securing, and transporting storage containers, radiographic exposure devices, and sealed radioisotope sources;
- The operating and emergency procedures;
- Actions to be taken if a dosimeter shows an off-scale reading or an alarm ratemeter alarms (sounds, etc.) unexpectedly;
- Procedures to be followed if a film badge, OSL, or similar device is lost or damaged; and
- Procedures for notifying the proper persons in the event of an accident.

Discussion: If an individual's self-reading pocket dosimeter is found to be off scale, an individual's electronic personal dosimeter reads above 2 mSv (200 mrem), or a ratemeter alarms (sounds, etc) unexpectedly, the RSO or designee must be notified immediately. If radiation exposure cannot be ruled out by the RSO or designee as the root cause, the individual's film badge, OSL or similar approved device must be sent for processing within 24 hours. The affected individual may not resume work with radioactive material until the RSO or designee has determined the individual's radiation exposure. **There are no exemptions to this requirement.**

If any of the events described above should occur, personnel should be instructed to do the following at a minimum:

- Stop work immediately, ensure that the source is in the safe storage position in the exposure device, and vacate the radiation area;
- If the ratemeter alarms (sounds, etc.), evaluate pocket dosimeter reading;
- Notify the individual specified in the emergency procedures;
- Notify the RSO or designee of the problem;
- If pocket dosimeter is off scale, do not resume operations until authorized by the RSO or designee; and
- If the exposure cannot be ruled out by the RSO or designee, then the film badge or OSL must be processed within 24 hours.

Response from Applicant:

Item 10.9.8 Ratemeter Alarms Or Off-Scale Dosimeter Readings (Check box)

We have addressed ratemeter alarms or off-scale dosimeters in the operating and emergency procedures

Item 10.9.9: Procedure For Identifying And Reporting Defects And Non-Compliance

Rule: 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1150, 12VAC5-481-1330 A, 12VAC5-481-1530

Criteria: Licensees must notify management if defects are found in radiography equipment.

Discussion: Equipment defects that cause a substantial safety hazard, or equipment failures involving VDH-regulated activities, must be reported to the agency. For example, a failure of the coupling between the source assembly and the control cable must be reported to the agency. Radiography personnel should be instructed to report any malfunction or defect in radiography equipment to management, so that management can take appropriate action.

Response from the Applicant:

Item 10.9.9 Procedure For Identifying And Reporting Defects And Non-Compliance (Check box)

We have included procedures for notifying management of equipment malfunction or defect in the operating and emergency procedures

Note: See NRC IN 91-39 'Compliance with 10 CFR part 21, Reporting of Defects and Non-compliance'. This is available from the NRC website at www.nrc.gov.

Item 10.9.10: Required Notifications

Rule: 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1150, 12VAC5-481-1250 D, 12VAC5-481-1330 A, 12VAC5-481-1520 B, 12VAC5-481-1530

Criteria: Operating and emergency procedures must ensure that appropriate notifications are made during and after an emergency.

Discussion: The emergency procedures should clearly identify the names and telephone numbers of the RSO or other persons who can provide assistance in an emergency or accident. Such persons may also include the exposure device manufacturer and the agency. The emergency procedures shall always be available to radiography personnel during radiography and up-to-date.

VDH rules also require immediate notification upon the discovery of certain events. Notify the agency when radiographic devices are lost or stolen or if there is indication of overexposure. Refer to the rule stated above or to **Appendix P** for additional guidance in the preparation of emergency procedures. **Table 9** below provides a description of events that require notification and/or reports.

Table 9: Required Notifications

EVENT	TEL. NOTIFICATION	WRITTEN REPORT	RULE
Fire, explosion or toxic gas release	Immediate	30 days	12VAC5-481-1100
Unplanned contamination event	24 hours	30 days	12VAC5-481-1100
Equipment is disabled or fails to function as designed	24 hours	30 days	12VAC5-481-1100
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
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
Whole body dose greater than 0.05 Sv (5 rems)	None	30 days	12VAC5-481-1110
Dose to minor greater than 5mSv (500 mrem)	None	30 days	12VAC5-481-1110
Dose to embryo or fetus of a declared pregnant woman greater than 5 msv (500 mrem)	None	30 days	12VAC5-481-1110
Dose to individual member of public greater than 1 mSv (100 mrems)	None	30 days	12VAC5-481-1110
Any applicable limit in the license or registration	None	30 days	12VAC5-481-1110
Leak test of sealed source or guide tube greater than 185 Bq (0.005 Ci)	None	5 days	12VAC5-481-1250 D
Unintentional disconnection of the source assembly from the control cable	None	30 days	12VAC5-481-1530 A
Inability to retract the source assembly to its fully shielded position and secure it in its retracted position	None	30 days	12VAC5-481-1530 A
Failure of any component which is critical to safe operation of the device to properly perform its intended function	None	30 days	12VAC5-481-1530 A
An indicator on radiation machine fails to show that radiation is being produced, and exposure switch fails to terminate production of radiation when turned to the off position or a safety interlock fails to terminate x-ray production	None	30 days	12VAC5-481-1530 A
Use of licensed material at any location not on license for more than 180 days in a calendar year	Notify the agency prior to exceeding 180 days	None	12VAC5-481-1530 C

Response from Applicant:

Item 10.9.10 Required Notifications (Check box)

We have included appropriate instructions for notifying the RSO and/or other personnel in the operating and emergency procedures.

Note: Telephone notifications shall be made to the agency at (804) 864-8150 during normal business hours (8 a.m. – 4:30 p.m.) For immediate notifications after normal business hours, the 24 hour emergency telephone number is (804) 674-2400 or (800) 468-8892. Identify the emergency as radiological.

Item 10.9.11: Minimizing Exposure Of Persons In The Event Of An Accident

Rule: 12VAC5-481-630, 12VAC5-481-1330 A

Criteria: To maintain exposures as low as possible in the event of an emergency.

Discussion: Since it is not possible to specify all possible situations that would constitute an emergency, a general instruction is acceptable. This general instruction should describe licensee actions to maintain the dose at a minimal level after an abnormal event is identified. The instruction should include routine emergency actions such as posting the restricted area, maintaining surveillance of the restricted area, and notifying the RSO.

General instructions that give a basic idea of how to react when something unexpected happens should include such direction as immediately move away from the source, while at a safe distance from the source and maintaining a low exposure, calm down and begin to survey to verify the boundary of the restricted area (2 mR/hr boundary). Remain at this boundary, but maintain visual surveillance of source. Contact RSO or designee; however, do not leave where you cannot maintain surveillance of source, send someone to the phone if necessary.

Response from Applicant:

Item 10.9.11 Minimizing Exposure Of Persons In The Event Of An Accident (Check box)

We have included instructions for minimizing exposure of persons in the event of an accident in the operating and emergency procedures

Item 10.9.12: Source Retrieval

Rule: 12VAC5-481-1330 A, 12VAC5-481-1530

Criteria: Each licensee who intends to perform source retrieval operations must have appropriate equipment, training, and procedures.

Discussion: Applicants must develop source retrieval procedures if their own radiographic personnel with appropriate training and experience will conduct source retrievals. If procedures are submitted, the agency will review and approve applicants to perform source retrieval. If source retrieval procedures are not submitted for review, then source retrieval activities must be conducted by a licensee whose is specifically authorized for these activities by VDH, NRC or another Agreement State.

Licensees specifically approved to perform source retrievals will have a specific license condition authorizing these activities. In addition, these individuals are authorized to perform source retrievals for other licensees.

The agency will review the applicant's procedures for source retrieval with respect to keeping exposures ALARA and controlling exposures to radiation. Since it is not possible to specify all potential exposure situations, a general procedure is acceptable.

A retrieval procedure should contain the following elements:

- Warnings that only specifically authorized individuals, or personnel supervised by such authorized individuals and working in their presence are allowed to perform retrievals;
- A clear statement that no source or suspected source containing items such as a stuck source in a guide tube will be handled directly;
- Expedient methods of reducing unintended exposure to staff and the public, such as using lead shot bags, sandbags, steel plates, remote handling devices, and culverts cut lengthwise;
- Additional dosimetry should be used during source retrievals, for example, pocket dosimeters with a range greater than 2 mSv (200 mrems) or finger badges;
- Methods of restricting access to the area, including establishing a restricted area and obtaining outside help in controlling access;
- Appropriate use of survey instruments. The procedure should prohibit using alarming dosimeters or electronic dosimeters as survey instrument substitutes;
- Criteria for requesting outside assistance;
- Instructions for reducing the exposure to other personnel and members of the public during recovery operations;
- Notification of the RSO/RSO-designee, and management;
- Specific training including practice with special tools, shielding, and additional dosimetry with a dummy source; and
- Notification to the agency.

Response from Applicant:

<p>Item 10.9.12 Source Retrieval (Check one box)</p> <p><input type="checkbox"/> We will not perform source retrieval and will use the services of a person specifically licensed by VDH, NRC or another Agreement State to perform the retrievals of our sources.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will perform source retrieval. We have included source retrieval procedures in the operating and emergency procedures and submit specific training for agency review.</p>
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Note: Radiography personnel should not attempt to perform operations involving retrieval or recovery unless they have actual training in retrieval operations using a dummy source with the appropriate handling tools, survey instruments, and dosimetry. Source retrieval must be specifically authorized on the license.

Item 10.9.13: Maintenance Of Records

Rule: 12VAC5-481-10, 12VAC5-481-100, 12VAC5-481-571, 12VAC5-481-980, 12VAC5-481-1330, 12VAC5-481-1350, 12VAC5-481-1360, 12VAC5-481-1390, 12VAC5-481-1430, 12VAC5-481-1440, 12VAC5-481-1450, 12VAC5-481-1480, 12VAC5-481-1490, 12VAC5-481-1500, 12VAC5-481-1520

Criteria: The licensee shall meet VDH record requirements.

Discussion: Personnel must generate and maintain certain records when performing radiography, including:

- Utilization logs showing the following:
 - Description, including the make, model, and serial number of the device used.
 - Identification and signature of the radiographer.
 - Where the device is used and dates of use; dates device is removed and returned to storage.
- Records of daily inspection of equipment;
- Pocket dosimeter readings. These readings must be made at the beginning and end of a work shift. Instructions to personnel must specify that the readings be recorded; and
- Results of the physical survey to ensure that the sealed source is in the shielded position, when a radiographic exposure device is placed in a storage area (as defined in 12VAC5-481-10) and if that survey is the last one performed in the workday.

Operations requiring records include inspections and maintenance at intervals not to exceed 3 months. Other examples include instrument calibration and shipment of packages. Radiography personnel should also be aware of the records that must be maintained at temporary jobsites listed in 12VAC5-481-1520 B. Radiographers performing radiographic duties should be given specific instructions for recordkeeping. These should not include instructions about records that are the responsibility of management and supervision.

Response from the Applicant:

Item 10.9.13 Maintenance Of Records (Check box)

We have included procedures which ensure proper maintenance of records in the operating and emergency procedures.

Item 10.10: Minimization of Contamination

Rule: 12VAC5-481-450 A, 12VAC5-481-1200, 12VAC5-481-1250

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. Industrial radiography applicants usually do not need to address these issues as a separate item since they are included in responses to other items of the application.

Sealed source and devices that are approved by the NRC or another Agreement State and located and used according to their respective SSDR Certificates usually pose little risk of contamination. Leak tests performed as specified in 12VAC5-481-1250 should identify defective sources. Leaking sources must be withdrawn from use and decontaminated, repaired, or disposed of according to 12VAC5-481, 'Virginia Radiation Protection Regulations'. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts. Other efforts to minimize radioactive waste do not apply to programs using only sealed sources and devices that have not leaked.

Note: The applicant does not need to provide a response to this item. The agency will consider that the above Criteria have been met if the applicant's responses meet the criteria for the following items: 'Sealed Sources and Devices', 'Facilities and Equipment', 'Leak Tests', 'Operating and Emergency Procedures', and 'Waste Management'.

Item 11: Waste Management

Rule: 12VAC5-481-100, 12VAC5-481-500, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-910, 12VAC5-481-980, 12VAC5-481-2980, 12VAC5-481-3100

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

Discussion: Licensees who dispose of radiography sealed sources, or dispose of radiography devices containing depleted uranium, must transfer them to an authorized recipient. Recipients authorized to accept radioactive material are the original manufacturer of the device, or a commercial firm licensed by VDH, the NRC or another Agreement State.

Before transferring radioactive material, a licensee must use one of the methods described in 12VAC5-481-570 D to verify that the recipient is properly authorized to receive it. In addition, all packages containing radioactive sources must be prepared and shipped in accordance with VDH/DOT requirements. Records of the transfer must be maintained as required by 12VAC5-481-571.

Response from Applicant:

<p>Item 11 Waste Management (Check box)</p> <p><input type="checkbox"/> We will return the radiography sealed source(s) to the manufacturer for disposal or transfer the radiography sealed source(s) to a specific licensee authorized by VDH, the NRC or another Agreement State to receive radioactive material.</p>
--

Note: Because of the difficulties and costs associated with disposal of sealed sources containing radioactive material and devices containing depleted uranium, applicants should preplan the disposal. Applicants may want to consider contractual arrangements with the sealed source and device supplier as part of a purchase agreement.

Item 12 License Fees

Rule: 12VAC5-490

Criteria: On VDH form, 'Application for a Radioactive Material License Authorizing the Use of Industrial Radiography' (**Appendix A**), enter the fee category and the amount of the fee enclosed with the application.

Response from Applicant:

SPECIFIC LICENSE FEE	
Item 12 License Fees (Refer to 12VAC5-490.)	
Category:	Application Fee Enclosed (For new applications): <input type="checkbox"/> Yes <input type="checkbox"/> No Amount Enclosed \$ _____

Item 13: Certification

Criteria:

- Individuals acting in a private capacity are required to sign and date VDH Form, 'Application for a Radioactive Material License Authorizing the Use of Industrial Radiography' (**Appendix A**).
- Senior representatives of a corporation or legal entity must sign and date VDH Form, 'Application for a Radioactive Material License Authorizing the use of Industrial Radiography' (**Appendix A**).

Representatives signing an application must be authorized to make binding commitments and sign official documents on behalf of the applicant. As discussed in the section titled 'Management Responsibility', signing the application acknowledges management's commitment and responsibilities for the radiation protection program. The agency will return all unsigned applications for proper signature.

Response from Applicant:

CERTIFICATION (To be signed by an individual authorized to make binding commitments on behalf of the applicant.)	
Item 13	
I hereby certify that this application was prepared in conformance with 12VAC5-481, 'Virginia Radiation Protection Regulations' and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.	
SIGNATURE - Applicant Or Authorized Individual	Date signed
Print Name and Title of above signatory	

Note:

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

Appendix A

VDH Form

‘Application for a Radioactive Material License Authorizing the Use of Industrial Radiography’

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



APPLICATION FOR A RADIOACTIVE MATERIAL LICENSE AUTHORIZING THE USE RADIOACTIVE MATERIAL FOR INDUSTRIAL RADIOGRAPHY

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

Instructions - Complete all items if this is an initial application or an application for renewal of a license. Refer to VAREG 'Guidance for Industrial Radiography Use.' Use supplementary sheets where necessary. Retain one copy and submit original of the entire application to: Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219.

APPLICATION TYPE

Item 1 Type Of Application (Check one box)

New License Renewal License Number _____

CONTACT INFORMATION

Item 2 Name and Mailing Address Of Applicant:

Item 3 Person To Contact Regarding Application:

Applicant's Telephone Number (Include area code):

Contact's Telephone Number (Include area code):

LOCATION OF RADIOACTIVE MATERIAL

Item 4 Location of Radioactive Material (Do not use Post Office Box):

Used
 Stored
 Used and Stored

Address:

Telephone Number
 (Include area code):

Permanent Cell Facility

Used
 Stored
 Used and Stored

Address:

Telephone Number
 (Include area code):

Permanent Cell Facility

Used
 Stored
 Used and Stored

Address:

Telephone Number
 (Include area code):

Permanent Cell Facility

Is industrial radiography performed at temporary job sites?: Yes No

RADIATION SAFETY OFFICER

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

- The name of the proposed RSO and other potential designees who will be responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

NAME: _____

TELEPHONE
NUMBER: _____
(Include area code)

AND

- We will demonstrate that the RSO has sufficient independence and direct communication with responsible management officials by providing a copy of an organizational chart by position and will confirm that the RSO has day-to-day oversight of the radiation safety activities.

AND EITHER

- We will provide the specific training and experience of the RSO. Include the following:
1. Specific dates of certification and/or training in radiation safety.
 2. Documentation to show that the RSO has a minimum of 2,000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations.
 3. Documentation to show that the RSO has obtained formal training in the establishment and maintenance of a radiation protection program.

OR

- We will provide alternative information demonstrating that the proposed RSO is qualified by training and experience (e.g. Board Certification by the American Board of Health Physicists, completion of a bachelor's and/or master's degree in the sciences with at least one year of experience in the conduct of a radiation safety program of comparable size and scope) documentation to show that the RSO has obtained formal training in the establishment and maintenance of a radiation protection program.

TRAINING FOR RADIOGRAPHERS AND RADIOGRAPHER'S ASSISTANTS

Item 6 Training For Radiographers and Radiographer's Assistants (Check box and attach requested information)

- We will submit the information outlined in section titled "Training for Radiographers and Radiographer's Assistants" in VAREG 'Guidance for Industrial Radiography Use'

RADIOACTIVE MATERIAL

Item 7 Sealed Source Radioactive Material (Attach additional pages if necessary)

Element and mass number	Sealed source manufacturer and model number
Maximum activity per source	Exposure device manufacturer and model number
Source changer manufacturer and model number	

Is Depleted Uranium used as a shielding material? Yes No

Only radiographic exposure devices, source assemblies or sealed sources, and associated equipment which meets the requirements specified in 12VAC5-481-1210 will be used in radiographic operations. Yes No

FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING

Item 8 Financial Assurance and Recordkeeping For Decommissioning (Check both boxes)

We shall maintain drawings and records important to decommissioning and will transfer these records to a new licensee before licensed activities are transferred in accordance with 12VAC5-481-490 B or assign the records to the agency before the license is terminated.

AND

If financial assurance is required, submit evidence per 12VAC5-481-450 C 6.

FACILITIES AND EQUIPMENT

Item 9 Facilities and Equipment (Check box and attach requested information)

We will submit the required information as listed in the section titled "Facilities and Equipment" of VAREG 'Guidance for Industrial Radiography Use'.

RADIATION SAFETY PROGRAM

Item 10 Radiation Safety Program

Item 10.1 Radiation Safety Program Audit

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

Item 10.2 Termination Of Activities (Check box)

We will notify the agency, in writing, within 60 days of the decision to permanently cease radioactive material use. (12VAC5-481-500)

Item 10.3 Instruments (Check all boxes that apply)

We will possess and use radiation survey meter(s) that meets the Criteria in the section titled "Instruments" in VAREG 'Guidance for Industrial Radiography Use'.

AND EITHER

If calibration is performed by a person or firm outside the applicant's organization, the calibration will be performed by a VDH, NRC or another Agreement State licensee specifically authorized to perform instrument calibration.

OR

We will follow the survey meter calibration procedures in accordance with Appendix J in VAREG 'Guidance for Industrial Radiography Use'.

OR

We will submit alternate procedures. (Procedures are attached)

Note: Identify the qualifications of the individuals who will perform the calibrations if performed by the applicant.

Item 10.4 Material Receipt and Accountability (Check box)

Quarterly physical inventories (not to exceed 3 months) will be conducted of all sealed sources and/or devices containing radioactive material (including depleted uranium) and the information contained in the discussion section titled "Material Receipt and Accountability" in VAREG 'Guidance for Industrial Radiography Use' will be documented.

Item 10.5 Leak Tests (Check one box)

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

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

Organization Name _____

License Number _____

Issuing Entity _____

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

OR

We will perform our own leak testing and sample analysis. We will follow the procedures in Appendix K of VAREG 'Guidance for Industrial Radiography Use.'

OR

We will submit alternative procedures. (Procedures are attached)

Item 10.6 Occupational Dosimetry (Check all boxes that apply)

- We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged monthly.
AND
- The required personnel monitoring equipment, including 0 to 2 mSv (200 mrem) dosimeters or electronic personal dosimeters, will be worn by radiographic personnel.
AND
- Alarm ratemeters set to alarm at 500 mrem/hour with an accuracy of plus or minus 20%, will be worn by all radiography personnel.
Note: Radiography personnel at permanent radiography installations where other appropriate alarming or warning devices are in use do not need alarming ratemeters.
AND
- Pocket dosimeters and alarm ratemeters will be checked for correct response at intervals not to exceed 12 months.
AND EITHER
- If adjustment is necessary, the devices will be returned to the manufacturer.
OR
- If adjustment is necessary, procedures for adjustments are described.

Item 10.7 Public Dose

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

Item 10.8 Quarterly Maintenance (Check both boxes)

- We have included procedures for quarterly maintenance as part of the operating and emergency procedures.
AND
- Before using a new sealed source/device combination, we will have written inspection and maintenance procedures that address the use of new equipment as a Type B transport package. In addition, we will provide training to radiographic personnel before using a new sealed source/device combination.

OPERATING AND EMERGENCY PROCEDURES

Item 10.9 Operating and Emergency Procedures

Operating and emergency procedures must be submitted to the agency for review.

Item 10.9.1 Handling and Use Of Sealed Sources and Radiography Exposure Devices (Check box)

- We have included the following in the operating and emergency procedures:
Step-by-step instructions for using each type of radiographic devices;
Instructions for performing source exchanges; and
Instructions for crankout devices should be separate from those for pipeliner devices.

Item 10.9.2 Methods and Occasions For Conducting Radiation Surveys (Check box)

- We have included in the operating and emergency procedures all surveys as described in the section titled "Methods and Occasions For Conducting Radiation Surveys" in VAREG 'Guidance for Industrial Radiography Use'.

Item 10.9.3 Methods For Controlling Access To Radiographic Areas (Check box)

- We have included procedures to control access to radiographic operations and storage areas in the operating and emergency procedures.

Item 10.9.4 Methods and Occasions For Locking and Securing Radiographic Exposure Devices, Storage Containers, and Sealed Sources (Check box)

- We have included procedures for locking and securing radiographic equipment in the operating and emergency procedures.

Item 10.9.5 Personnel Monitoring and The Use Of Personnel Monitoring Equipment (Check box)

- We have included instructions for proper use of personnel monitoring equipment in the operating and emergency procedures.
-

Item 10.9.6 Transporting Sealed Sources To Field Locations, Securing Exposure Devices and Storage Containers In Vehicles, Posting Vehicles, and Controlling Sealed Sources During Transportation (Check one box)

We have included procedures for transporting sealed sources containing radioactive material, exposure devices, and source changers in the operating and emergency procedures.

OR

Not Applicable (Devices are not transported)

Item 10.9.7 Daily Inspection and Maintenance Of Radiography Equipment (Check box)

We have included procedures for daily inspection and maintenance of radiography equipment in our operating and emergency procedures.

Item 10.9.8 Ratemeter Alarms Or Off-Scale Dosimeter Readings (Check box)

We have addressed ratemeter alarms or off-scale dosimeters in the operating and emergency procedures.

Item 10.9.9 Procedure For Identifying and Reporting Defects and Non-Compliance (Check box)

We have included procedures for notifying management of equipment malfunction or defect in the operating and emergency procedures.

Item 10.9.10 Required Notifications (Check box)

We have included appropriate instructions for notifying the RSO and/or other personnel in the operating and emergency procedures.

Item 10.9.11 Minimizing Exposure Of Persons In The Event Of An Accident (Check box)

We have included instructions for minimizing exposure of persons in the event of an accident in the operating and emergency procedures.

Item 10.9.12 Source Retrieval (Check one box)

We will not perform source retrieval and will use the services of a person specifically licensed by VDH, the NRC or another Agreement State to perform the retrievals of our sources.

OR

We will perform source retrieval. We have included source retrieval procedures in the operating and emergency procedures and submit specific training for agency review.

Item 10.9.13 Maintenance Of Records (Check box)

We have included procedures which ensure proper maintenance of records in the operating and emergency procedures.

WASTE MANAGEMENT

Item 11 Waste Management (Check box)

We will return the radiography sealed source(s) to the manufacturer for disposal or transfer the radiography sealed source(s) to a specific licensee authorized by VDH, the NRC or another Agreement State to receive radioactive material.

SPECIFIC LICENSE FEE

Item 12 License Fees (Refer to 12VAC5-490.)

Category:

Application Fee Enclosed (For new applications):

Yes No Amount Enclosed \$

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

Item 13

I hereby certify that this application was prepared in conformance with 12VAC5-481 'Virginia Radiation Protection Regulations' and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.

SIGNATURE - Applicant Or Authorized Individual

Date signed

Print Name and Title of above signatory

Appendix B

VDH Form

'Certificate of Disposition of Material'

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



CERTIFICATE OF DISPOSITION OF MATERIALS

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

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

CONTACT INFORMATION

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

TERMINATION AND DISPOSITION INFORMATION

The following information is provided in accordance with 12VAC5-481-510. (Check all that apply)

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

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

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

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

Issued by (Licensing Agency):

- Decayed, surveyed and disposed of as non-radioactive waste.
- No radioactive material has ever been procured and/or possessed by the licensee under the authorization granted by the above referenced license.
- Other (Attach additional pages)

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

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

Name:

Address:

Contact Person Telephone Number: () - X

Additional remarks (Attach additional pages if necessary.)

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

Item 10.

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

SIGNATURE - Applicant or Authorized Individual

Date signed

Print Name and Title of Above Signatroy

Appendix C
Sample Correspondence Delegation Letter

SAMPLE CORRESPONDENCE DELEGATION LETTER

[date]

[name and address]

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 Material License to [name of designee]. [Name of designee] has management approval to sign and submit amendment requests to the Virginia Department of Health on behalf of [name of licensee]. I understand that license renewals must still be signed by a representative of upper management.

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

Signature

Title

Date

Print Name

Appendix D

Reserved

Appendix E

Information Needed for Transfer of Control Application

Information Needed for Transfer of Control Application

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

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

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

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

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

References: The information above is derived from Information Notice 89-25, Revision 1, "*Unauthorized Transfer of Ownership or Control of Licensed Activities*," which is available at the NRC's webpage at <http://www.nrc.gov>.

Appendix F

NRC Regulatory Issue Summary 2005-10 'Performance-Based Approach for Associated Equipment in 10 CFR 34.20'

ADDRESSEES

All industrial radiography licensees and manufacturers and distributors of industrial radiography equipment.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to explain the performance-based approach NRC has decided to take regarding the requirements in

10 CFR 34.20, "*Performance requirements for industrial radiography equipment*", which addresses the regulation of associated equipment used in an industrial radiography system. This RIS supersedes and replaces Information Notice 96-20, "*Demonstration of Associated Equipment Compliance with 10 CFR 34.20*". No specific action or written response is required.

BACKGROUND

In the *Federal Register* notice (68 FR 41757, July 15, 2003), NRC announced its denial of the petitioner's request for rulemaking to remove from **10 CFR 34.20** the term "*associated equipment*". The notice also explained that NRC's practice of registering associated equipment under **10 CFR 32.210**, "*Registration of product information*", which was previously described in Information Notice 96-20, had been discontinued. This RIS supersedes and replaces Information Notice 96-20.

SUMMARY OF ISSUE

To maintain safety, each licensee must take special care to ensure that all associated equipment (including modified or customized associated equipment) meets the minimum performance criteria required in **10 CFR 34.20**. A licensee that modifies associated equipment is required to demonstrate by actual testing or an alternative analysis that the performance of the radiographic system and individual items of associated equipment meet the criteria in **10 CFR 34.20**. The results of actual testing or analysis must demonstrate that the replacement component will not compromise the design safety features of the industrial radiography system. Compliance with the performance criteria prevents a licensee from using substandard associated equipment.

PERFORMANCE REQUIREMENTS FOR ASSOCIATED EQUIPMENT

The performance requirements for associated equipment are set forth in the paragraphs of **10 CFR 34.20**, described below:

- paragraph (a)(1), incorporates by reference the American National Standards Institute (ANSI) N432-1980, "*Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography*", (ANSI N432) which specifies the design and method of qualifying (testing) industrial radiography equipment, including equipment that NRC has defined as "*associated equipment*";
- paragraph (a)(2), provides for an engineering analysis as an alternative to actual testing, to demonstrate the performance of individual radiography equipment components;
- paragraph (b)(3), allows associated equipment to be modified unless the replacement component would compromise the design safety features of the industrial radiography system;
- paragraph (c)(5) and (8), respectively address crushing and kinking tests for a guide tube and the standard test for tensile strength of an exposure head;
- paragraph (e), allows a licensee or vendor to apply a realistic torque to the drive mechanism during the life cycle test.

The regulations require a licensee to use industrial radiography equipment that has been manufactured and tested to meet radiation safety performance criteria under **10 CFR 34.20**.

The life cycle test in ANSI N432 is an evaluation of the endurance of a source or device. To test the life cycle of an industrial radiography source or exposure device, all components of the industrial radiography system (including the associated equipment) must be assembled and operated for the duration of the test. This requirement, NRC determined, is sufficient to maintain safety and a separate regulatory approval for associated equipment is not needed as long as the associated equipment meets the minimum criteria in **10 CFR 34.20**.

Attachment 1 to this RIS contains additional information about definitions and applicable requirements, certificates of registration for a sealed source or device, custom-built items of associated equipment, acceptable methods to demonstrate compliance, inspection and licensing guidance, and inspection and maintenance procedures. Attachment 2 indicates the availability of reference documents that are cited in this RIS and Attachment 1.

ENFORCEMENT POLICY

The NRC Enforcement Policy, Supplement VI, provides examples of violations in each of the four severity levels as guidance in determining the appropriate severity level for violations in the area of fuel cycle and materials operations, including industrial radiographic operations. An example of an activity that would normally result in the NRC issuing a Severity Level III Notice of Violation is possession or use of unauthorized equipment or materials in the conduct of licensee activities that degrades safety. Based on this example, enforcement action would be considered for a licensee that used associated equipment that had not been tested or analyzed to meet the performance requirements or that used modified associated equipment that compromised the design safety features of an industrial radiography system and threatened or did not protect the health and safety of workers or members of the public.

AGREEMENT STATE COMPATIBILITY

NRC has determined that the information provided in this RIS does not change the level of compatibility of the Agreement State regulations to the existing NRC requirements. Use of the information in this RIS continues to provide Agreement States with the flexibility to revise their policy and guidance to meet unique situations and local conditions and to ensure an orderly, uniform implementation of the performance-based approach for associated equipment.

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment on this RIS was not published in the *Federal Register* because it is informational, and does not represent a departure from current regulatory requirements.

SMALL BUSINESS REGULATORY ENFORCEMENT FAIRNESS ACT

NRC has determined that this action is not subject to the Small Business Regulatory Enforcement Fairness Act of 1996.

PAPERWORK REDUCTION ACT STATEMENT

This RIS requires no specific action or written response. If you have any questions about this summary, please contact one of the individuals listed below or the appropriate regional office.

/RA/ Thomas Essig for
Patricia K. Holahan, Acting Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical Contacts: J. Bruce Carrico, NMSS
301-415-7826
E-mail: jbc@nrc.gov

Thomas Young, NMSS
301-415-5795
E-mail: tfy@nrc.gov

Note: NRC generic communications may be found on the NRC public Web site, <http://www.nrc.gov>, under Electronic Reading Room/Document Collections.

Attachments: 1. Additional Information and Applicable Requirements Regarding Associated Equipment
2. Availability of Reference Documents

Attachment 1

ADDITIONAL INFORMATION AND APPLICABLE REQUIREMENTS REGARDING ASSOCIATED EQUIPMENT

Definitions

10 CFR 34.3, “*Definitions*”, defines associated equipment as equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source [e.g., guide tube, control tube, control (drive) cable, removable source stop, ‘J’ tube, and collimator when it is used as an exposure head]. **10 CFR 34.3** defines the following items of associated equipment: collimator, control (drive) cable, control (drive) mechanism, control tube, exposure head (source stop), and guide tube. **10 CFR 34.3** defines the following radiographic equipment and related terms: radiographic exposure device, s-tube, sealed source, source assembly, source changer, and storage container.

Licensees should be aware of the specific meaning of the terms indicated above. The requirements applicable to items of equipment depend on how the equipment is defined in **10 CFR 34.3**. It is important to distinguish between items of equipment that are considered to be associated equipment and items of equipment that are not. In some cases, there may be no regulatory requirements that apply to an item of equipment; in other cases, an item of equipment may be a component of a source or device that is required to be specifically authorized for use. Following are two examples that illustrate important distinctions which determine regulatory requirements for an item of equipment.

The first example distinguishes certain types of collimators that are not associated equipment and are not required to meet the performance criteria in ANSI N432. Various types of collimators are used as radiation safety devices for industrial radiographic operations. In many cases, the exposure head at the end of the guide tube is inserted into a collimator. This type of collimator is not an item of associated equipment because the source does not come in contact with the collimator. This type of collimator is not subject to the performance requirements in **10 CFR 34.20** or the evaluation process in **10 CFR 32.210**. However, if a collimator does come in contact with the source because it also acts as a source stop (exposure head), then it falls within the scope of the definition of associated equipment that is subject to the performance requirements in **10 CFR 34.20**.

The second example distinguishes the connector that is located between the sealed source and the control (drive) cable. **10 CFR 34.3** defines the source assembly to include the connector, stating, “*Source assembly means an assembly that consists of the sealed source and a connector that attaches the source to the control cable*”. The connector is a component of the source assembly and is, therefore, not an item of associated equipment. The source assembly is subject to the

requirements in **10 CFR 30.32**, "*Application for a specific license*". **10 CFR 30.32(g)** indicates that an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains a sealed source must either identify the sealed source or the device as registered under **10 CFR 32.210** or with an Agreement State or must include the information identified in **10 CFR 32.210(c)**. The manufacturing processes used to attach the connector to the source cable and to the control (drive) cable are also subject to evaluation by NRC or an Agreement State under these requirements.

Portable industrial radiographic systems typically include a two-piece connector (swivel coupling design) to attach the source assembly to the control (drive) cable in order to operate the system. The performance-based requirement in **10 CFR 34.20(c)(1)** indicates that the coupling must be designed such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions. The Statements of Consideration at 55 FR 843 (January 10, 1990) include a response to comments received for **10 CFR 34.20(c)(1)**. The response indicates, "*NRC's source and device registration process will ensure compliance with this performance requirement by requiring NRC approval before the newly designed connectors could be used*". The sealed source or device evaluation process ensures compliance with the performance criteria in the rule. Both pieces of the two-piece connector are subject to evaluation under **10 CFR 30.32(g)** or **32.210(c)**.

Sealed Source and Device (SS&D) Certificate of Registration

NRC determined that the previous practice of registering associated equipment under **10 CFR 32.210** was not only not required, but was a regulatory practice that imposed an unnecessary burden on licensees and for NRC and the Agreement States which are authorized to evaluate SS&Ds. Therefore, this practice has been discontinued. NRC does not intend to independently revise current SS&D certificates of registration only to remove references to associated equipment. If it becomes necessary to amend a current SS&D certificate of registration, the applicant may remove or update the information about associated equipment in the application.

As a matter of convenience, an SS&D applicant under **10 CFR 32.210** may describe the associated equipment that was used in the life cycle test for the radiographic source or device that is being registered; however, there is no requirement to do so. If an applicant wants the associated equipment to be included on the certificate of registration, the application which describes associated equipment must include sufficient information to demonstrate that the performance criteria were met for associated equipment under **10 CFR 34.20**. If a certificate of registration does not identify the associated equipment that was used in the system along with the source or device, then each end-user (licensee) must demonstrate that the items of associated equipment which the licensee uses in the system meet the performance criteria under **10 CFR 34.20** and do not compromise the design safety features of the system.

NUREG-1556, Volume 3, Revision 1, "*Consolidated Guidance About Materials Licenses—Applications for Sealed Source and Device Evaluation and Registration*", (Final Report, April 2004), Section 4.6, "*Radiography Equipment*", indicates that there is no requirement to identify associated equipment for an SS&D certificate of registration. **Note**—In Section 15, "*Glossary*", the definition of "*associated equipment*" was intended to be removed and should be disregarded because it has been superseded by Section 4.6.

Custom-Built or Unique Items of Associated Equipment

Associated equipment specifically designed and constructed to the order of a single licensee must comply with the performance criteria in **10 CFR 34.20**. There is no requirement to register custom-built or unique items of associated equipment. However, when modified or custom-built associated equipment introduces components or fabrication methods that differ from those that

were used in the endurance test for a source assembly or exposure device that was previously registered, the licensee must demonstrate compliance with the requirements in **10 CFR 34.20** before the equipment can be used for industrial radiographic operations. For example, licensees must obtain information demonstrating that modified guide tubes and exposure heads will withstand tests that demonstrate the equipment will maintain its integrity in normal use and likely accident conditions.

Acceptable Methods to Demonstrate that Associated Equipment Complies with 10 CFR 34.20

The performance-based approach that NRC has decided to take for associated equipment recognizes that a licensee has latitude to use modified components, unless the design of any replacement component would compromise the design safety features of the system. Further guidance about testing or an alternative analysis to testing is described in NUREG-1556, Volume 3, Revision 1, Section 10.5, "*Prototype Testing*". The NUREG addresses appropriate methods a licensee may use to demonstrate the ability of a modified industrial radiography system to maintain its integrity when subjected to conditions of normal use and likely accident conditions.

For example, information about an equivalent system that was previously registered may be used to demonstrate safety and integrity of the modified system, if the design of the modified system and its intended normal and likely accident conditions of use are identical or similar to the previously registered system. In some cases, an engineering analysis or operational history with supporting documentation may be sufficient for a licensee to justify the use of a modified system without repeating, e.g., an endurance test. However, when an appropriate comparison to the previously registered system is not possible because a licensee is unable to obtain appropriate information about previous prototype testing, engineering analysis, or operational history for the previously registered system or item of associated equipment, then the licensee must complete actual testing of the modified system and the individual items of associated equipment to demonstrate compliance with **10 CFR 34.20**.

NRC contracted a testing laboratory to complete actual testing of three industrial radiography systems from three manufacturers. The contractor developed procedures to test the systems and individual items of associated equipment to meet the performance criteria in **10 CFR 34.20**. In a similar manner, a licensee could contract a testing laboratory or manufacturer of industrial radiography equipment to test or analyze a modified system or component that will be used in a system that was previously licensed or registered.

If a licensee needs to modify associated equipment, the licensee should adopt and implement a suitable engineering procedure or plan to ensure that a modified component will not compromise the design safety features of the industrial radiographic system. Implementation of such a procedure or plan should demonstrate that modifications to the equipment: (1) will not create material incompatibility that may degrade a sealed source or device over the expected useful life time; (2) will not diminish the performance of the system in expected use environments and in likely accident conditions over the expected life time of the various system components; (3) will not allow a source to inadvertently exit the system; and (4) will not initiate or propagate equipment failures resulting in a "source disconnect." An endurance test for a modified system should indicate that the modified component does not interfere with the performance of the components of the system that were previously registered.

Examples of the performance-based approach that NRC has decided to use for **10 CFR 34.20** are included in the following paragraphs to illustrate situations when a licensee must complete testing or analysis of associated equipment to demonstrate that the associated equipment meets

the performance criteria in **10 CFR 34.20** and does not compromise the design safety features of the system.

It is acceptable for a licensee to assume that no further testing is needed for associated equipment which is listed along with the source or device as an entire system on the certificate of registration because the associated equipment has already been verified to meet the performance criteria in **10 CFR 34.20** when the associated equipment is used with the source or device. However, a licensee that substitutes associated equipment into an industrial radiography system that was registered as an entire system which specified the associated equipment must demonstrate that the reconfigured system meets the performance criteria under **10 CFR 34.20**.

It is acceptable for a licensee to assume that associated equipment that is used as the manufacturer intended as described in the SS&D certificate of registration meets the performance criteria under **10 CFR 34.20**. The SS&D certificate of registration indicates the principal use, normal conditions of use, and the limitations on use for the source or device. However, a licensee that uses associated equipment in a manner that was not intended by the manufacturer as described in the SS&D certificate of registration for the source or device must describe the conditions of use for the equipment and obtain information about performance of the equipment under these conditions of use to demonstrate compliance with **10 CFR 34.20**. Conditions of use include, for example, extremely hot or cold operating temperature, excessive vibration or shock, high concentrations of corrosive materials, and underwater usage.

Inspection and Licensing Guidance

NRC is revising inspection and licensing guidance to incorporate the explanation provided by this RIS. Inspection Procedure 87121, "*Industrial Radiography Programs*", directs an inspector to follow a performance-based approach to examine available associated equipment, observe work in progress that involves use of associated equipment, and interview workers about the inspection and maintenance procedures and the worker's awareness that associated equipment must comply with the performance criteria in **10 CFR 34.20**.

If the associated equipment appears to be modified or defective, the inspector should verify whether or not the licensee had developed and implemented a testing program to demonstrate that modified components meet the performance criteria in **10 CFR 34.20**. The inspector should alert the inspection supervisor who may extend the inspection and request an SS&D reviewer to evaluate the licensee's modification of the equipment. The expectation is that the design safety features of the industrial radiography system were not compromised by a replacement component of associated equipment that was modified by the licensee. Before using the modified system, the licensee is required to demonstrate that the replacement component meets the performance criteria in **10 CFR 34.20**.

NUREG-1556, Volume 2, "*Consolidated Guidance about Materials Licensees—Program-Specific Guidance about Industrial Radiography Licenses*" (Final Report, August 1998) is being amended to remove statements that indicate associated equipment must be specifically approved or registered by NRC or an Agreement State. Instead, the guidance will state that vendors or distributors of industrial radiography equipment may voluntarily include the items of associated equipment that were used in the system with their SS&Ds that are registered under **10 CFR 32.210**. To include associated equipment in the certificate of registration, the vendor's application must include information that demonstrates the associated equipment meets the minimum criteria in **10 CFR 34.20**. Also, copies of this RIS will be inserted into Appendix F to replace Information Notice 96-20.

Inspection and Maintenance Procedures

NRC completed a generic assessment and special team inspection which was published in NUREG-1631, "*Source Disconnects Resulting from Radiography Drive Cable Failures*" (June 1998). The inspection team observed that, in general, radiography exposure devices appeared to be in good working order, showing no evidence of damage, abuse, or lack of maintenance. By contrast, the associated equipment (i.e., control mechanisms, including drive cables) often appeared to be damaged, in disrepair, and lacking maintenance.

NUREG-1631 emphasized the importance of a licensee's understanding and commitment to the operating and use conditions specified by a vendor (manufacturer or distributor) of an industrial radiography system which, if exceeded, could compromise the safety and reliability of the system. This is particularly true of items of associated equipment, including drive cables. A licensee should be vigilant to inspect and maintain associated equipment in order to avoid component failures that could result in unnecessary radiation exposures to workers and members of the public.

A licensee's equipment inspection and maintenance program should prevent particular equipment problems that may develop from excessive uses where harsh or abusive conditions exist that may cause a component to fail. **10 CFR 34.31**, "*Inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments*", requires a licensee to perform visual and operability checks on associated equipment before use on each day the equipment is to be used to ensure that the equipment is in good working condition. If equipment problems are found, the equipment must be removed from service until repaired. In addition, the licensee is required to have written procedures for inspection and routine maintenance of associated equipment at intervals not to exceed three months or before the first use thereafter to ensure the proper functioning of components important to safety. Replacement components shall meet design specifications. If problems are found, the equipment must be removed from service until repaired. Records are required for equipment problems and any maintenance performed.

Attachment 2

AVAILABILITY OF REFERENCE DOCUMENTS

Below are the titles of the reference documents along with the URLs and the ADAMS accession numbers (e.g., MLxxxxxxx), if available. The URLs link directly to the documents that are posted on the NRC's public web site. For documents without an URL, NRC maintains an Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. These documents may be accessed through the NRC's Public Electronic Reading Room on the Internet at <http://www.nrc.gov/reading-rm/adams.html>. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800- 397-4209, 301-415- 4737, or by e-mail to pdr@nrc.gov. If no URL or ADAMS accession number is indicated for the document then send a written request for a single, paper copy of the document to the Office of Administration, Distribution and Mail Services Section, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; or contact the PDR noted above.

1. Federal Register notice (68 FR 41757, July 15, 2003), Denial of a petition for rulemaking [Docket No. PRM-34-5, Amersham Corporation] ML050620568

2. 10 CFR Part 32, Specific domestic licenses to manufacture or transfer certain items containing byproduct material <http://www.nrc.gov/reading-rm/doc-collections/cfr/part032/>
3. 10 CFR Part 34, Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations <http://www.nrc.gov/reading-rm/doc-collections/cfr/part034/>
4. American National Standards Institute (ANSI) N432–1980, Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography, (ANSI N432) ML050840139
5. NRC Enforcement Policy <http://www.nrc.gov/what-we-do/regulatory/enforcement/enforc-pol.pdf>
6. NUREG-1556, Volume 3, Revision 1, Consolidated Guidance About Materials Licenses–Applications for Sealed Source and Device Evaluation and Registration, (Final Report, April 2004) ML041340618 <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v3/r1/>
7. Inspection Procedure 87121, Industrial Radiography Programs, <http://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/ip87121.pdf>
8. NUREG-1556, Volume 2, Consolidated Guidance about Materials Licensees–Program-Specific Guidance about Industrial Radiography Licenses (Final Report, August 1998) <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v2/>
9. NUREG-1631, Source Disconnects Resulting from Radiography Drive Cable Failures (June 1998)

Appendix G

Radiographer and Radiographer's Assistant Training

Radiographer's Training

REFERENCE	REQUIREMENT	TRAINING CRITERIA
12VAC5-481-1320	Training Classroom Training – 40 hours in Length	Topics in 12VAC5-481-1320 A & B Fundamentals of Radiation Safety <ul style="list-style-type: none"> • Characteristics of gamma radiation • Units of radiation dose and quantity of radioactivity • Hazards of exposure to radiation • Levels of radiation from licensed material • Methods of controlling radiation dose (time, distance, and shielding) Radiation Detection Instruments <ul style="list-style-type: none"> • Use, operation, calibration and limitations • Survey techniques • Personnel monitoring equipment Equipment to be Used <ul style="list-style-type: none"> • Operation and control of radiographic exposure equipment, remote handling equipment, storage containers and pictures or models of source assemblies (pigtailed) • Storage, control and disposal of licensed material • Inspection and maintenance of equipment Requirements of 12VAC5-481, 'Virginia Radiation Protection Regulations' Case Histories of Accidents in Radiography
	On-the-Job Training- 2 months or 320 hours	Under the supervision of a qualified radiographer
	Certification by a Certifying Entity	Certified through a radiographer certification program meeting the requirements of 10 CFR 34 Appendix A

12VAC5-481-1320	Must Receive Copies of and Instruction in:	12VAC5-481 Parts: <ul style="list-style-type: none"> • IV • V • X • XIII 12VAC5-481-30 The License The Licensee's Operating & Emergency Procedures
	Written Examination of items listed above	Successful completion
12VAC5-481-1320 B	Receive Equipment Training	Training includes: <ul style="list-style-type: none"> • Exposure devices • Sealed sources • Associated equipment • Survey meters • Daily inspection
	Demonstrate Understanding in Use of Equipment by Practical Exam	Successful completion
12VAC5-481-1320 D	Annual Refresher Training	Review the following: <ul style="list-style-type: none"> • Radiation Safety review • New procedures or equipment • New rule requirements • Observations and deficiencies during audits and discussion of any significant incidents or accidents involving radiography • Employee questions
12VAC5-481-1470	Records of Training and Certification	Maintained in accordance with rule

Radiographer's Assistant Training

REFERENCE	REQUIREMENT	TRAINING CRITERIA
12VAC5-481-1320 C	Must Receive Copies of and Instruction in:	12VAC5-481 Parts: <ul style="list-style-type: none"> • IV • V • X • XIII 12VAC5-481-30 The License The Licensee's Operating & Emergency Procedures
	Written Examination of items listed above	Successful completion
12VAC5-481-1320 C	Receive Equipment Training	Training under the supervision of a qualified radiographer that includes: <ul style="list-style-type: none"> • Exposure devices • Sealed sources • Associated equipment • Survey meters • Daily inspection
	Demonstrate Understanding in Use of Equipment by Practical Exam	Successful completion
12VAC5-481-1320 D	Annual Refresher Training	Review the following: <ul style="list-style-type: none"> • Radiation Safety review • New procedures or equipment • New rule requirements • Observations and deficiencies during audits and discussion of any significant incidents or accidents involving radiography • Employee questions
12VAC5-481-1470	Records of Training and Certification	Maintained in accordance with rule

Appendix H

Six-Month Radiographer/Radiographer's Assistant Inspection Checklist

Six-Month Radiographer/Radiographer's Assistant Inspection Checklist

Date: _____ Time: _____	
Radiographic Location: _____	
Radiographer/Radiographer's Assistant: _____	
Device Model No.: _____	Serial No.: _____
Survey Meter Functionality: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Calibrated: <input type="checkbox"/> Yes <input type="checkbox"/> No	Daily Source Check: <input type="checkbox"/> Yes <input type="checkbox"/> No
Dosimetry: OSL, Film Badge, Or Similar Device and Pocket Dosimeter: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Pocket Dosimeter Calibrated: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Alarming Dosimeter: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Calibrated: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Daily Operational Check Performed: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Were other individuals working within the restricted area wearing film badges, OSLs or similar devices, dosimeters and alarm dosimeters?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Was the restricted area posted with a "CAUTION (or DANGER) RADIATION AREA" sign(s)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Was the restricted area properly controlled to prevent unauthorized entry?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Was the high-radiation area posted with a "CAUTION (OR DANGER) HIGH RADIATION AREA" sign(s)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Was the utilization log properly filled out?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Did the radiographer/radiographer's assistant have sufficient knowledge of safety rules?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Was the radiographer working with properly inspected and operable equipment?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Did the radiographer/radiographer's assistant properly survey the camera?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Did the radiographer properly supervise the radiographer's assistant?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Was the camera properly locked and secured to prevent unauthorized removal?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Was the restricted area properly controlled?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Was the high radiation area under continuous direct observation except where entry had been prevented?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Were radioactive isotopes stored properly and kept locked to prevent removal?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Was the storage area posted with a "CAUTION (or DANGER) RADIOACTIVE MATERIAL" sign(s)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Did the radiographer/radiographer's assistant possess and use a copy of the operating and emergency procedures and VDH rules for protection against radiation?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Were there any other safety items found to be lacking? If yes, explain in Remarks.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Remarks/Comments: _____ _____ _____ _____	

Appendix I

Radiation Protection Program Audit

Radiation Protection Program Audit

Date of this Audit: _____
Audit: _____
Next Audit Date: _____

Date of Last

Auditor _____
(Signature)

Date _____

Management Review _____
(Signature)

Date _____

Organization and Scope of Program

A. Organizational structure. (specify any changes)

1. Matches license requirements. [L/C]
2. Multiple authorized locations of use and/or field sites authorized.
3. List of location(s) inspected - attached or reference.
4. Brief description of scope of activities, including types of equipment, types and quantities of use involving radioactive material, frequency of use, staff size, etc.

B. Radiation Safety Officer.

1. Named on license. [L/C]
2. Fulfills duties as RSO. [12VAC5-481-1310 A & D]
3. Meets requirements. [12VAC5-481-1310 B & C]

C. Radiographers and radiographer's assistants named in documents. [L/C]

Training, Retraining, and Instructions to Workers

A. Instructions to workers. [12VAC5-481-2270]

B. 12VAC5-481-30 and Parts: III, V, X, and XII; the license; and operating and emergency procedures are furnished to all radiographers and radiographer's assistants. [12VAC5-481-1320]

C. Training program description the same as that submitted with license application or as amended?

[12VAC5-481-1200 A]

1. Written tests completed by all radiographers and radiographer's assistants.
2. Oral tests.
3. All radiographers completed on-the-job training.
4. Periodic training program implemented.
5. Records maintained [12VAC5-481-1470].

D. Workers cognizant of requirements for:

1. Radiation safety program. [12VAC5-481-630]
 - a. Occupational exposure annual limits. [12VAC5-481-640]
 - b. Public annual dose limits. [12VAC5-481-720]

2. 10% monitoring threshold. [12VAC5-481-760]
3. Dose limits to embryo/fetus and declared pregnant worker. [12VAC5-481-710]
4. Procedures for opening packages. [12VAC5-481-900]

Operating and Emergency Procedures

- A. Procedures current? [12VAC5-481-1520 B]
- B. Procedures contain information specified. [12VAC5-481-1330 A]
- C. Procedures submitted to the agency. [L/C]

Internal Audits or Inspections

- A. Audits/inspections of each radiographer and radiographer's assistants conducted at 6-month intervals or after as appropriate. [12VAC5-481-1320 E]
- B. Equipment check before use each day. [12VAC5-481-1270]
- C. Equipment inspection and maintenance performed at 3-month intervals. [12VAC5-481-1270 D]
- D. Records maintained. [12VAC5-481-1390, 12VAC5-481-1410, 12VAC5-481-1420, 12VAC5-481-1430, 12VAC5-481-1440, 12VAC5-481-1450, 12VAC5-481-1460, 12VAC5-481-1490, 12VAC5-481-1500, 12VAC5-481-1510, 12VAC5-481-1520]

Facilities

- A. Permanent radiographic installation. [12VAC5-481-1280]
 1. High Radiation Area posted. [12VAC5-481-860]
 2. Entrance controls are as described. [12VAC5-481-1280 A]
 - a. Visible and audible radiation signals.
 - b. Visible signal actuates if entry is attempted when source is exposed.
 - c. Audible signal actuates if entry is attempted when source is exposed.
 - d. System tested daily with radiation source.
 - e. Records maintained for 3 years. [12VAC5-481-1460]
- B. Temporary High Radiation Area Entry Controlled. [12VAC5-481-1370]
- C. Storage Area
 1. Storage Facilities as Described in license. [L/C]
 2. Sources Locked in Devices. [12VAC5-481-1230 A]
 3. Devices secured to prevent tampering or unauthorized removal. [12VAC5-481-1290 C]

Equipment

- A. Radiography devices, source assemblies and source changers in use meet requirements. [12VAC5-481-1210]

- B. Associated equipment in use complies with requirements. [12VAC5-481-1210 C]
- C. Source changers and storage containers meet radiation level limits. [12VAC5-481-1220]
- D. Equipment exempted by specific license condition is used in accordance with license commitments and authorization.

Materials

- A. Isotope, chemical/physical form, quantity and use as authorized on the license. [L/C]
- B. All sealed sources not fastened to or contained in an exposure device are tagged. [12VAC5-481-1210 C]
- C. Leakage and contamination tests.
 - 1. Sealed sources.
 - a. Leak test method approved. [12VAC5-481-1250 C]
 - b. Leak tests performed at 6 month intervals. [12VAC5-481-740, 12VAC5-481-1250 C]
 - c. Leakage is less than 185 becquerels (Bq) (0.005 microcuries).
 - 2. Depleted uranium (DU) shielding with S-tubes.
 - a. Test every 12 months. [12VAC5-481-1250 E]
 - b. DU is less than 185 Bq (0.005 microcuries).
 - 3. Records maintained for 3 years. [12VAC5-481-1420]
- D. Inventories
 - 1. Conducted quarterly (not to exceed 3 months). [12VAC5-481-1260]
 - 2. Contain all required information. [12VAC5-481-1430 B]
 - 3. Records maintained for 3 years. [12VAC5-481-1430 A]
 - 3. Most recent inventory conducted on _____
- E. Utilization Logs
 - 1. Utilization logs maintained. [12VAC5-481-1440]
 - 2. Contain all required information. [12VAC5-481-1440]

Instrumentation

- A. Describe the survey instruments possessed:
 Model No. _____ Quantity _____
- B. Capable of measuring 0.02 mSv (2 mrem)/hr through 0.01 Sv (1 rem)/hr. [12VAC5-481-1240 A]
- C. Operable and calibrated survey instruments available and used on each job. [12VAC5-481-1240]
- D. Calibration performed at intervals not to exceed six months or after servicing. [12VAC5-481-1240 B]
- E. Records maintained for 3 years. [12VAC5-481-1410]

Radiation Surveys

- A. Area or facility surveys conducted to show compliance with 12VAC5-481-720 and 12VAC5-481-730. [12VAC5-481-750]
- B. Records maintained. [12VAC5-481-1000]
- C. Survey after each exposure, including device, guide tube, ensuring source has returned to the shielded position. [12VAC5-481-1360]
- D. Survey of device when place in storage to ensure source is in shielded position. [12VAC5-481-1360]
- E. Protection of members of the public [12VAC5-481-720]
 - 1. Adequate surveys made to demonstrate.
 - a. The TEDE to the individual likely to receive the highest dose does not exceed 0.1 mSv (100 mrem) in a year;
 - Or
 - b. That if an individual were continuously present in an unrestricted area, the external dose would not exceed 1 mSv (100 mrem) in a year. [12VAC5-481-730]
 - 2. Unrestricted area radiation levels do not exceed 0.02 mSv (2 mrem) in any 1 hour. [12VAC5-481-720]
 - 3. Records maintained. [12VAC5-481-1050]

Personnel Radiation Protection

A. Dosimetry

- 1. Workers monitored as required. [12VAC5-481-1350]
- 2. Exchange Frequency _____ Supplier _____
- 3. Verify supplier is NVLAP-approved. [12VAC5-481-750]
- 4. Dosimetry exchanged at required frequency. [12VAC5-481-1350 A]
- 5. Dosimetry records maintained. [12VAC5-481-1490]

B. Pocket Dosimeters and Electronic Personal Dosimeters [12VAC5-481-1350]

- 1. Model No. _____ Range _____
Model No. _____ Range _____
- 2. Read and recorded at start of each shift.
- 3. Daily readings recorded.
- 4. Dosimeters checked for response ($\pm 20\%$) at intervals not to exceed 12 months.
- 5. Off-scale dosimeter procedure and records.

C. Alarm Ratemeters [12VAC5-481-1350]

- 1. Model No. _____ Range _____
- 2. Checked that alarm functions properly at start of each shift.
- 3. Preset at 5 mSv (500 mrem)/hr.
- 4. Calibrated to $\pm 20\%$ at intervals not to exceed 12 months.
- 5. Records maintained.

D. Dosimetry Reports

- 1. Reviewed by _____ Frequency _____
- 2. Reviewed personnel monitoring records for interval (from _____ to _____).

3. Maximum exposures: TEDE _____ extremity, other _____.
4. VDH Forms (or equivalent). [12VAC5-481-1000, 12VAC5-481-1040]
5. Maximum exposures in compliance with annual limits. [12VAC5-481-640]
6. Fetal and Pregnant worker exposure. [12VAC5-481-710]
 - a. Worker declared pregnancy in writing during the audit interval.
 - b. If yes, licensee in compliance? Records maintained?
7. Dosimetry records maintained. [12VAC5-481-1490]
8. Annual exposure reports given to workers who receive > 100 mrem per year? [12VAC5-481-2280]

E. Radiation Protection Program [12VAC5-481-630]

1. Program includes provisions for keeping dose ALARA.
2. Procedures and engineering controls used to achieve ALARA.
3. Content and implementation reviewed annually by licensee.
4. Records of program reviews maintained.

F. Planned Special Exposures (PSEs) [12VAC5-481-690]

1. PSEs performed? _____
2. If so, when, where and why? _____
3. Records maintained.

Receipt and Transfer of Radioactive Material [12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-900, 12VAC5-481-1400]

- A. Procedures established and followed for picking up, receiving, and opening packages.
- B. Incoming packages surveyed.
- C. Shipment of sources since last inspection.
 1. Used container authorized by license or Certificate of Compliance (COC).
 2. Transfers.
 3. All sources surveyed before shipment and transfer.
- D. Records of surveys and receipt/transfer maintained. [12VAC5-481-1400]

Transportation [12VAC5-481-2980 and 49 CFR 170-189]

A. Shipments are:

- Delivered to common carriers.
- Transported in company's private vehicle.
- Both.
- No shipments since last audit.

B. HAZMAT training [49 CFR 172.700- 172.704]

C. Packages:

1. Authorized packages used. [49 CFR 173.415; 173.416]
2. Performance test records on file.
 - a. Special form sources. [49 CFR 173.476(a)]
 - b. DOT-7A packages. [49 CFR 173.415(a)]

3. COC's on file with NRC for Type B. [10 CFR 71.12(c)(1)]
4. Two labels with Transport Index, Nuclide, Hazard Class. [49 CFR 172.403; 172.441]
5. Properly marked (Shipping name, UN number, Package type, RQ, Name and address of consignee.
[49 CFR 172.301; 172.310; 172.324; 172.101]
6. Closed and sealed during transport. [49 CFR 173.475(f)]

D. Shipping papers

1. Prepared and used. [49 CFR 172.200(a)]
2. Proper (Shipping name, Hazard class, UN number, Quantity, Package type, Nuclide, RQ, Radioactive material, Physical and chemical form, Category of label, TI, Shipper's name, Certification and signature, Emergency response phone number, "Limited Quantity" "Cargo Aircraft Only" if applicable). [49 CFR 172.200 - 172.204; 175.700]
3. Readily accessible during transport.

E. Vehicles

1. Placarded. [49 CFR 172.504]
2. Cargo blocked and braced. [49 CFR 177.842(d)]
3. Proper overpacks (shipping name, UN number label, statement of inner packaging complies with specification packaging). [49 CFR 171.15; 171.16]

F. Any transportation incidents reported to DOT National Response Center [49 CFR 171.15; 171.16]

Auditor's Independent Measurements

A. Survey Instrument: _____
 Serial No.: _____
 Last Calibration: _____

B. Auditor's measurements were compared with audited person's measurement

C. Describe the type, location, and results of measurements, attach a diagram/survey sheet and refer to this section

Notifications and Reports

A. Reports to individuals, public and occupational, monitored to show compliance [12VAC5-481-1030, 12VAC5-481-1040, 12VAC5-481-1050, 12VAC5-481-1120, 12VAC5-481-1130, 12VAC5-481-2280]

B. Theft or loss [12VAC5-481-1090]

C. Incidents [12VAC5-481-1100]

D. Overexposures and high radiation levels [12VAC5-481-1110]

E. Annual reports furnished to the agency

F. Reporting of defects and non-compliance [12VAC5-481-1530]

Posting and Labeling

- A. Radiation areas [12VAC5-481-860]
- B. High radiation areas [12VAC5-481-860]
- C. Use or storage areas [12VAC5-481-860]
- D. Containers or devices labeled [12VAC5-481-880, 12VAC5-481-1290]
- E. Notice to employee form [12VAC5-481-2260 C]

Recordkeeping for Decommissioning [12VAC5-481-450 C]

- A. Records in independent and identifiable location
- B. Records include all required data

Bulletins and Information Notices

- A. Communications received and reviewed
- B. Appropriate response to Information Notices

Special License Conditions or Issues

Evaluate special license conditions for data, actions

Performance Evaluation Factors

These indicators may provide an indication of the status of the Radiation Safety Program as perceived by management.

- A. Lack of senior management involvement with the radiation safety program and/or RSO oversight
- B. RSO too busy with assignments other than radiation safety
- C. Insufficient staffing
- D. Radiation Safety Committee fails to meet or functions inadequately
- E. Inadequate consulting service or inadequate audits

Appendix J

Procedure for Calibrating Survey Instruments

Procedure for Calibrating Survey Instruments

A. Sealed source(s) used for calibrating survey instruments should:

1. Approximate a point source
2. Have its exposure rate at a given distance traceable by documented measurements to a standard certified to be within +/- 5% accuracy by NIST
3. Approximate the same photon energy (Ir-192, Co-60) as the source to be used in the radiography device.
4. Be of sufficient strength to give an exposure rate of about 0.3 mSv/hr (30 mrem/hr) at 100 cm. (85 mCi of Cs-137 or 21 mCi of Co-60).

B. Use the inverse square and radioactive decay law to correct changes in exposure rate due to source decay or different distances from the source.

C. Record survey meter calibration data and maintain written records for each instrument being used to satisfy regulatory requirements. Survey meter calibration reports should indicate the procedure used and the data obtained. Calibration records should contain the following information and must be maintained 3 years from date of calibration of each instrument:

1. Owner or user identification, including name, address, and person to be contacted;
2. Instrument description that includes manufacturer, model number, serial number, and type of detector;
3. Calibration source description that includes exposure rate, indicated exposure rate at a specified distance on a specified date, and the calibration procedure;
4. Each calibration point identifying the calculated exposure rate, the indicated exposure rate, the deduced correction factor, and the scale selected on the instrument;
5. Exposure reading indicated with the instrument in the 'battery check' mode, if available;
6. Angle between the radiation flux field and the detector (parallel, perpendicular);
Note: Internal detectors should specify angle between radiation flux field and a specified surface of the instrument
7. For detectors with removable shielding, note whether the shielding was in place or removed during the calibration procedure;
8. Include person's name who performed the calibration and the date on which the calibration was performed;

D. A single point on a survey meter scale can be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 10%.

Note: Three kinds of scales are frequently used on radiation survey meters:

1. Linear Scale: Meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be at approximately 1/3 and 2/3 of the decade.
2. Multidecade Logarithmic Scale: Meters that have a multidecade logarithmic scale must be calibrated at no less than one point on each decade and no less than two points on one of the decades. Those points should be approximately 1/3 and 2/3 of the decade.
3. Automatically Ranging Digital Display: Meters that have a device for indicating rates must be calibrated at no less than one point on each decade and at no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.

E. Scales in excess of 10 mSv/hr (1,000 mrem/hr) need not be calibrated. However, such scales should be checked for operation and approximately correct response.

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

1. Source that was used to calibrate the instrument
2. A calibration chart or graph for each scale or decade of a survey meter that is greater than $\pm 20\%$ of the actual values identifying the average correction factor, or a note indicating that scale was checked only for function or is inoperative.
3. Date of calibration
4. Date survey instrument is due calibration
5. Name or initials of individual calibrating instrument.

Note: Detailed information about survey instrument calibration may be obtained by referring to ANSI N323-1978, "*Radiation Protection Instrumentation Test and Calibration*". Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018.

NUREG 1556, Volume 18 'Program-Specific Guidance About Service Provider Licenses' is available from the NRC website at www.nrc.gov.

Appendix K

Requests to Perform Leak Testing and Sample Analysis

Requests to Perform Leak Testing and Sample Analysis

A. Requests to Perform Leak Testing and Sample Analysis

1. Identify the individual who will make the analysis and provide his or her qualifications to make quantitative measurements of radioactivity.
2. Specify how and where test samples will be taken on the radiography device. Describe materials used and methods of handling samples to prevent or minimize exposure to personnel.
3. Specify the type of instrument(s) that will be used for measurement, the counting efficiency, and minimum levels of detection for each radionuclide to be measured.

Note: An instrument capable of making quantitative measurements should be used; hand-held survey meters will not normally be considered adequate for measurements.

4. Specify the standard sources used to calibrate the instrument; for each, specify the radionuclide, quantity, accuracy, and tractability to primary radiation standards.

Note: Accuracy of standards should be within $\pm 5\%$ of the stated value and traceable to a primary radiation standard such as those maintained by the National Institutes of Standards and Technology (NIST).

NUREG 1556, Volume 18 'Program-Specific Guidance About Service Provider Licenses' is available at the NRC website: www.nrc.gov, or from DHFS upon request.

5. Include a sample calculation for conversion of the measurement data to Bq(or microcuries).
6. Provide instructions on actions to take and persons to be notified if sources are found to be leaking.

B. Procedure for Performing Leak Testing and Analysis

1. For each source to be tested, list identifying information such as radiography device serial number, radionuclide, activity.
2. If available, use a survey meter to monitor exposure.
3. Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
4. Number each wipe to correlate with identifying information for each source.
5. Wipe the most accessible area where contamination would accumulate if the sealed source were leaking.
6. Using the instrument identified to and approved by VDH, count and record background count rate.
7. Check the instrument's counting efficiency using standard source of the same radionuclide as the source being tested or one with similar energy characteristics.

8. Calculate efficiency.
9. Count each wipe sample; determine net count rate.
10. For each sample, calculate and record estimated activity in Bq (or microcuries).
11. Sign and date the list of sources, data and calculations.
12. If the wipe test activity is 185 Bq (0.005 microcurie) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly. Also notify the agency.

C. Sampling and Analysis for Depleted Uranium as a Result of S-tube Breakthrough

Note: As an ALARA and safety measure, the source should be transferred to a source changer before the S-tube is tested for breakthrough.

1. The wipe test sample should be obtained from the areas of the tube where wear is likely to be most severe, at the first curve nearest the ends of the radiography device. The sample should be analyzed for alpha contamination. Alpha contamination present indicates that wear has broken through the S-tube to expose the depleted uranium.
2. Alpha counting sensitivity should be able to detect 185 Bq (0.005 microcuries) of contamination.
3. A worn S-tube could create equipment operating difficulties. Upon verification of the presence of alpha-particle emitting uranium, the radiographic exposure device should be removed from use until an evaluation of the wear of the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. No user repairs are permitted.

Appendix L

Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

A. Licensees must ensure that:

1. The radiation dose received by individual members of the public resulting from the licensee's possession and/or use of licensed materials does not exceed 1 mSv (100 mrem) in one calendar year.

Members of the public include persons who live, work, or may be near locations where industrial radiography devices are used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where devices are used or stored.

2. The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.

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

3. Licensees must show compliance with both portions of the rule. Radiographic operations at temporary jobsites must be demonstrated to have doses to the public in unrestricted areas that do not exceed 0.02 mSv (2 mrem) in any one hour. For storage areas and permanent radiographic facilities, calculations or a combination of calculations and measurements (e.g., using an environmental TLD) are often used to prove compliance with levels of 0.02 mSv (2 mrem) in any one hour and 1mSv (100 mrem) in a calendar year.

B. Calculation Method

1. For ease of use by most industrial radiography licensees, the examples in this Appendix use conventional units. The conversions to SI units are as follows: 1 foot (ft) = 0.305 meter (m); 1 mrem = 0.01 mSv.
2. The calculation method takes a tiered approach, going through a three-part process starting with a worst case situation and moving toward more realistic situations. It makes the following simplifications: (1) each device is a point source, (2) typical radiation levels encountered when the source is in the shielded position are taken from either the Sealed Source & Device (SSD) Registration Sheet, the maximum dose levels allowed for a transport package (exposure device) labeled YELLOW III, or the manufacturer's literature, and (3) no credit is taken for any shielding found between the devices and the unrestricted areas.
3. Part 1 of the calculation method is simple but conservative. It assumes that a member of the public is present 24 hours a day, and it uses only the inverse square law to determine if the distance between the device and the affected member of the public is sufficient to show compliance with the public dose limits. Part 2 considers not only distance, but also the time that a member of the public is actually in the area under consideration. Part 3 considers distance and the portion of time that both the device and the affected member of the public are present. Part 4 considers the distance, the portion of time that both the device and the affected member of the public are present and the shielding provided by the

structural materials or shielding materials specifically added by the licensee. Using this approach, licensees make only those calculations that are needed to demonstrate compliance. In many cases, licensees will need to use the calculation method through Part 1 or Part 2. These calculations typically result in higher radiation levels than would exist at typical facilities, but provide a method for estimating conservative doses which could be received.

C. Example 1

1. To better understand the calculation method, Mo-Rad, Inc., a hypothetical radiography licensee, is demonstrated. Yesterday, the company's president noted that the new device storage area is close to his secretary's desk and he asked Joe, the Radiation Safety Officer (RSO), to determine if the company is complying with VDH regulations.
2. The secretary's desk is near the wall separating the reception area from the designated, locked device storage area, where the company is storing its two devices. Joe measures the distances from each device to the wall and assumes that each device would have the maximum dose rate allowed under VDH rule or DOT regulations: 2 mSv/hr (200 mrem/hr) on the surface and 0.1 mSv/hr (10 mrem/hr) at one meter.

D. Findings

1. Upon his inspection, Joe found that there were two sources in the room. One Ir 192 device (Type B container) had a reading of 10 mrem/hr at 1 meter (3.3 ft) and was 12 ft from the secretary's chair. The other was a Co-60 device (Type B container) had a reading of 10 mrem/hr at 1 meter (3.3 ft) and was 18 ft from the secretary's chair.

E. Example 1: Part 1

1. Joe's first thought is that the distance between the devices and the secretary's chair may be sufficient to show compliance with the regulation in 10 CFR 20.1301. So, taking a worst case approach, he assumes: 1) the devices are constantly present (i.e., 24 hr/d), 2) both devices remain in storage with no other use, and 3) the secretary is constantly sitting in the desk chair (i.e., 24 hr/d). Joe proceeds to calculate the dose she might receive hourly and yearly from each device, as shown in **Tables 10** and **11** below.

F. Table 10: Calculation Method, Part 1: Hourly and Annual Dose Received from Device 1

Step No.	Description	Device 1 Input Data	Results
1	Dose received in an hour at known distance from device (e.g., from manufacturers data), in mrem/hr	10	10
2	Square of the distance (ft) at which the Step 1 rate was measured, in ft ²	(3.3) ²	10.9
3	Square of the distance (ft) from the device the secretary's desk in an unrestricted area, in ft ²	(12) ²	144
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	10 x 10.9	109
5	Divide the result of Step 4 by the result of Step 3 to calculate the dose received by an individual at the secretary's desk, HOURLY DOSE RECEIVED FROM DEVICE 1, in mrem in an hour.	109/144	0.76
6	Multiply the result of Step 5 by 24 hr/d x 365 d/yr = MAXIMUM ANNUAL DOSE RECEIVED FROM DEVICE 1, in mrem in a year.	0.76 x 24 x 365	6,630

G. Table 11: Calculation Method, Part 1: Hourly and Annual Dose Received from Device 2

Step No.	Description	Device 1 Input Data	Results
1	Dose received in an hour at known distance from device (e.g., from manufacturers data), in mrem/hr	10	10
2	Square of the distance (ft) at which the Step 1 rate was measured, in ft ²	(3.3) ²	10.9
3	Square of the distance (ft) from the device the secretary's desk in an unrestricted area, in ft ²	(18) ²	324
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	10 x 10.9	109
5	Divide the result of Step 4 by the result of Step 3 to calculate the dose received by an individual at the secretary's desk, HOURLY DOSE RECEIVED FROM DEVICE 2, in mrem in an hour.	109/324	0.34
6	Multiply the result of Step 5 by 24 hr/d x 365 d/yr = MAXIMUM ANNUAL DOSE RECEIVED FROM DEVICE 2, in mrem in a year.	0.34 x 24 x 365	2,950

H. To determine the total hourly and total annual dose received, Joe adds the pertinent data from the preceding tables.

Table 12: Calculation Method, Part 1: Total Hourly and Annual Dose Received from Devices 1 and 2

Step No.	Description	Device 1	Device 2	Sum
7	TOTAL HOURLY DOSE RECEIVED from Step 5 of Tables 9 and 10 , in mrem in an hour	0.76	0.34	0.76 + 0.34 = 1.1
8	TOTAL ANNUAL DOSE RECEIVED from Step 6 of Tables 10 and 11 , in mrem in a year	6,630	2,950	9,580

Note: The Sum in Step 7 demonstrates compliance with the limit of 2 mrem in any one hour. Reevaluate if assumptions change. If the Sum in Step 8 exceeds 100 mrem/yr, proceed to Part 2 of the calculational method. At this point, Joe is pleased to see that the total dose that an individual could receive in any one hour is only 1.1 mrem in an hour, but notes that an individual could receive a dose of 9,580 mrem in a year, much higher than the 100 mrem limit.

I. Example 1: Part 2

1. Joe reviews his assumptions and recognizes that the secretary is not at the desk 24 hr/d. He decides to make a realistic estimate of the number of hours the secretary sits in the chair at the desk, keeping his other assumptions constant (i.e., the devices are constantly present (i.e., 24 hr/d), both devices remain in storage with no other use). He then recalculates the annual dose received.

2. Table 13: Calculation Method, Part 2: Annual Dose Received from Devices 1 and 2

Step No.	Description	Results
9	A. Average number of hours per day that individual spends in area of concern (e.g., secretary sits at desk 5 hr/day; the remainder of the day the secretary is away from the desk area copying, filing, etc.) B. Average number of days per week in area (e.g., secretary is part time and works 3 days/week) C. Average number of weeks per year in area (e.g., secretary works all year)	5 3 52
10	Multiply the results of Step 9.A. by the results of Step 9.B. by the results of Step 9.C. = AVERAGE NUMBER OF HOURS IN AREA OF CONCERN PER YEAR	$5 \times 3 \times 52 = 780$
11	Multiply the sum in Step 7 by the results of Step 10 = ANNUAL DOSE RECEIVED FROM DEVICES CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN, in mrem in a year	$1.1 \times 780 = 860$

Note: If Step 11 exceeds 100 mrem in a year, proceed to Part 3 of the calculation method.

- Although Joe is pleased to note that the calculated annual dose received is significantly lower, he realizes it still exceeds the 100 mrem in a year limit.

J. Example 1, Part 3

- Again Joe reviews his assumptions and recognizes that the devices are not always in storage when the secretary is seated at the desk. As he examines the situation, he realizes he must consider each device individually.
- Summary of Information: Device #1 (Ir-192 Exposure Device) is located in the storage area overnight and used every day at temporary jobsites all year long; it is returned to the storage location at the end of each day meaning it is only present for the secretary's first and last hours of work each day. Device #2 (Co-60 Exposure Device) is in the storage area continuously (24 hr/d) for 8 months of the year and at a temporary jobsite for the remaining 4 months. The secretary is sitting at the desk 5 hours/day, 3 days/week and 52 weeks/year.

3. Table 14: Calculation Method, Part 3: Annual Dose Received from Devices 1 and 2

Step No.	Description	Device 1	Device 2
12	Average number of hours per day device is in storage while secretary is present	2	5
13	Average number of days per week device is in storage while secretary is present	3	3
14	Average number of weeks per year device is in storage while secretary is present	52	32
15	Multiply the results of Step 12 by the results of Step 13 by the results of Step 14 = TOTAL HOURS EACH DEVICE IS STORED PER YEAR WHILE SECRETARY IS PRESENT	$2 \times 3 \times 52 = 312$	$5 \times 3 \times 32 = 480$
16	Multiply the results of Step 15 by the results of Step 7 = ANNUAL DOSE RECEIVED FROM EACH DEVICE, in mrem in a year	$312 \times 0.76 = 237$	$480 \times 0.34 = 163$
17	Sum the results of Step 16 for each device = TOTAL ANNUAL DOSE RECEIVED CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN AND TIME DEVICE IS IN STORAGE, in mrem in a year	$237 + 163 = 400$	

Note: If the result in Step 17 is greater than 100 mrem/yr, the licensee must take corrective actions.

4. Joe notes that the result in Step 17 does not show compliance with the 100 mrem/yr limit. Since the result in Step 17 is higher than 100 mrem/yr, then Joe has to consider one or more of the following:

- Consider whether the assumptions used to determine occupancy and the time each device is in storage are accurate, revise the assumptions as needed, and recalculate using the new assumptions.
- Calculate the effect of any shielding located between the device storage area and the secretarial workstation. Listed below are typical half-value layers (HVL) for Ir-192 and Co-60.

5. Table 15: Half Value Layers (HVL) for Typical Shielding Materials

	Steel	HVL (inches) Lead	Concrete
Ir-192	0.5	0.25	1.7
Co-60	0.8	0.5	2.1

- Take corrective action (e.g., move devices within storage area, move the storage area, move the secretarial workstation) and perform new calculations to demonstrate compliance.
- Designate the area outside the storage area as a restricted area and the secretary as an occupationally exposed individual. This would require controlling access to the area for purposes of radiation protection and training the secretary as required by 10 CFR 19.12.

K. Example 1, Part 4

1. Joe decides to take into account the amount of shielding provided by the wall between the secretary's desk and the storage area where the two devices are located. The wall between the secretary's office and the storage area is a 4 inch thick concrete fire wall.

2. Table 16: Calculation Method, Part 4: Annual Dose Received from Devices 1 and 2

Step No.	Description	Device 1	Device 2
18	Annual dose received from each device from Step 15	237	163
19	Number of HVLs (Thickness of shielding material/Thickness for one HVL); If more than one shielding material, need to evaluate each shielding material separately by type of radionuclide	$4.0/1.7 = 2.35$	$4.0/2.1 = 1.9$
20	Fraction of radiation dose transmitted through shield: 0.5 (Total Number of HVLs); If more than one shielding material, then sum the number results from Step 19 by radionuclide	$0.5(2.35) = 0.2$	$0.5(1.9) = 0.27$
21	Multiply the results of Step 20 by the results of Step 18 = ANNUAL DOSE RECEIVED FROM EACH DEVICE, in mrem in a year	$0.2 \times 237 = 47$	$0.27 \times 163 = 44$
22	Sum the results of Step 21 for each device = TOTAL ANNUAL DOSE RECEIVED CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN, TIME DEVICE IS IN STORAGE AND SHIELDING OF STRUCTURAL MATERIALS, in mrem in a Year	$47 + 44 = 91$	

Note: If the result in Step 22 is greater than 100 mrem/yr, the licensee must take corrective actions.

3. Joe is glad to see that the results in Step 22 show compliance with the 100 mrem in a calendar year limit.
4. Note that in the example, Joe evaluated the unrestricted area outside only one wall of the device storage area. Licensees also need to make similar evaluations for other unrestricted areas and to keep in mind the ALARA principal, taking reasonable steps to keep radiation dose received below regulatory requirements. In addition, licensees need to be alert to changes in situations (e.g., moving any of the devices closer to the secretarial workstation, adding a device to the storage area, changing the secretary to a full-time worker, or changing the estimate of the portion of time spent at the desk) and to perform additional evaluations, as needed.

RECORD KEEPING: 12VAC5-481-1050 requires licensees to maintain records demonstrating compliance with the dose limits for individual members of the public.

L. Combination Measurement - Calculation Method

1. This method, which allows the licensee to take credit for shielding between the device and the area in question, begins by measuring radiation levels in the areas, as opposed to using manufacturer-supplied rates at a specified distance from each device. These measurements must be made with calibrated survey meters sufficiently sensitive to measure background levels of radiation. However, licensees must exercise caution when making measurements

with currently calibrated radiation survey instruments. A maximum dose of 1 mSv (100 mrem) received by an individual over an interval of 2080 hours (i.e., a work year of 40 hr/wk for 52 wk/yr) is equal to less than 0.5 microsievert (0.05 mrem) per hour.

This rate is well below the minimum sensitivity of most commonly available G-M survey instruments.

2. Instruments used to make measurements for calculations must be sufficiently sensitive. An instrument equipped with a scintillation-type detector (e.g., NaI(Tl)) or a micro-R meter used in making very low gamma radiation measurements should be adequate.
3. Licensees may also choose to use environmental TLDs. TLDs used for personnel monitoring (e.g., LiF) may not have sufficient sensitivity for this purpose. Generally, the minimum reportable dose received is 0.1 mSv (10 mrem). Suppose a TLD monitors dose received and is changed once a month. If the measurements are at the minimum reportable level, the annual dose received could have been about 1.2 mSv (120 mrem), a value in excess of the 1 mSv/yr (100 mrem/yr) limit. If licensees use TLDs to evaluate compliance with the public dose limits, they should consult with their TLD supplier and choose more sensitive TLDs, such as those containing CaF₂ that are used for environmental monitoring in unrestricted areas next to the device storage area for monitoring. This direct measurement method would provide a definitive measurement of actual radiation levels in unrestricted areas without any restrictive assumptions. Records of these measurements can then be evaluated to ensure that rates in unrestricted areas do not exceed the 1 mSv/yr (100 mrem/yr) limit.

M. Example 2

1. As in Example 1, Joe is the RSO for Mo-Rad, Inc., a radiography licensee. The company has two devices stored in a designated, locked storage area that adjoins an unrestricted area where a secretarial workstation is located. See **D** for information. Joe wants to see if the company complies with the public dose limits at the secretarial station.
2. During the winter while all the devices were in storage, Joe placed an environmental TLD badge in the secretarial workspace for 30 days. Joe chose a winter month so he did not have to keep track of the number of hours that each device was in the storage area. The TLD processor sent Joe a report indicating the TLD received 100 mrem.

3. Table 17: Combination Measurement - Calculation Method

Step No.	Description	Input Data and Results
Part 1		
1	Dose received by OSL, in mrem	100
2	Total hours OSL exposed	224 hr/d x 30 d/month = 720
3	Divide the results of Step 1 by the results of Step 2 to determine HOURLY DOSE RECEIVED, in mrem in an hour	0.14
4	Multiply the results of Step 3 by 365 d/yr x 24 hr/d = 8760 hours in one year = MAXIMUM ANNUAL DOSE RECEIVED FROM DEVICES, in mrem in a year	365 x 24 x 0.14 = 8760 x 0.14 = 1226
Part 2		
Adjust for realistic estimates of the time the secretary spends in the area as in Part 2 of Example 1.		
Part 3		
Adjust for realistic estimates of time devices spend in area of concern as in Part 3 of Example 1.		

Note: For the conditions described above, Step 3 indicates that the dose received in any one hour is less than the 2 mrem in any one hour limit. However, if there are any changes, then the licensee would need to reevaluate the potential doses which could be received in any one hour. Step 4 indicates that the annual dose received would be much greater than the 100 mrem in a year allowed by the rule.

4. In Step 2, Joe can adjust for a realistic estimate of the time the secretary spends in the area as he did in Part 2 of Example 1.
5. If the results of Joe's evaluation in Part 2 show that the annual dose received in a year exceeds 100 mrem, then he can make adjustments for realistic estimates of the time spent in the area of concern while the devices are actually in storage as in Part 3 of Example 1. (Recall that the TLD measurement was made while all the devices were in storage -- i.e., 24 hr/d for the 30 days that the TLD was in place.)

Appendix M

Information for Applicants to Consider When Developing Procedures for Operating Radiography Equipment

Information for Applicants to Consider When Developing Procedures for Operating Radiography Equipment

A. Crank-out Device

1. Locate the source shield at the desired distance from the object to be radiographed.
2. Mount the source tip firmly, using jigs or other attachments, with the tip in the exact exposure position.
3. Locate the control unit at the maximum distance (25 feet or 7.6 meters) from the source shield with the control tubes laid out as straight as possible.
4. Join the control cable to the unit following the manufacturer's instructions.
5. Establish and post the restricted area and high radiation area.
6. Unlock the device.
7. Turn the hand crank steadily to move the source out of the source shield to the exposure position.
8. Survey the perimeter of the restricted area to be sure that radiation levels do not exceed 0.02 mSv (2 mrem) in any one hour.
9. Maintain continuous surveillance over the restricted area during an exposure, keeping all persons from entering.
10. After completing the exposure, retract the source by turning the crank until the "safe" position is indicated.
11. Survey the entire circumference of the device and the guide tube to determine that the source is in a shielded position.
12. Lock the device and remove the key.

B. Pipeliner Device

1. Establish and post the restricted area and high radiation area.
2. Unlock the device.
3. Stand as far away as possible and out of the direction of the beam and expose the source
4. Survey the perimeter of the restricted area to be sure that the radiation levels do not exceed 0.02 mSv (2 mrem) in any one hour.
5. Maintain continuous surveillance over the restricted area during an exposure, keeping all persons from entering.
6. After completing the exposure, return the source to the shielded position.
7. Survey the device to determine that the source is in a shielded position.
8. Lock the device.

Note: The agency considers the following very important: surveys of the restricted area, continuous surveillance of the restricted area during an exposure, the survey of the device and guide tube, and locking the device.

C. Source Exchange

1. Removing the Old Source

Caution: Always use a calibrated, operable survey meter while performing a source exchange!

- a. Survey the shipping container upon receipt with a survey meter. Note that the surface reading should not exceed 2 mSv/hr (200 mem/hr).
- b. Attach the end of the source guide tube to the exposure device.
- c. Connect the other end of the source guide tube to the empty side of the source changer.
- d. Unlock the empty side of the source changer.

- e. Unlock the camera and crank out the source from the camera into the source changer.
- f. Survey the source changer and guide tube to verify that the source is in the safe position.
- g. Lock the source changer.
- h. Disconnect the source guide tube and drive cable to the source pigtail. Replace the dust cap on the source changer.
- i. Remove the source identification plate from the exposure device and affix the plate to the side of the source changer loaded with the old source.

2. Installing the New Source

- a. Remove the dust cap on the source changer lock body identified with the new source tag.
- b. Align the camera and source guide tube with the source changer.
- c. Connect the new source to the drive cable.
- d. Connect the source guide tube to the source changer.
- e. Unlock the source changer and retract the new source into the exposure device.
- f. Survey the exposure device and guide tube to assure that the source is in the safe position.
- g. Lock the exposure device.
- h. Disconnect the source guide tube and drive accessories.
- i. Affix the new source identification plate on the exposure device.

Appendix N
Transportation

Transportation

The following are the major areas in DOT regulations most relevant for transporting radiographic exposure devices and source exchangers that are shipped as Type B quantities are:

- A. Table of Hazardous Materials and Special Provisions [**49 CFR 172.101**]
 - 1. **49 CFR 172.101** - Hazardous Materials Table [proper shipping name, hazard class, identification number]
 - 2. **Table 2, Appendix A, 49 CFR 172.101** - List of Hazardous Substances and Reportable Quantities [for radionuclides]

- B. Shipping Papers - **49 CFR 172.200**
 - 1. **49 CFR 172.201** - General entries [on shipping papers]
 - 2. **49 CFR 172.202** - Description of hazardous material on shipping papers
 - 3. **49 CFR 172.203** - Additional description requirements
 - 4. **49 CFR 172.204** - Shipper's certification [if applicable]

- C. Package Markings - **49 CFR 172.300**
 - 1. **49 CFR 172.301** - General marking requirements for non-bulk packaging
 - 2. **49 CFR 172.304** - Marking requirements
 - 3. **49 CFR 172.310** - Radioactive material [Type B]
 - 4. **49 CFR 172.324** - Hazardous substances in non-bulk packaging [designation of "*reportable quantities*" with the letters "*RQ*"]

- D. Package Labeling - **49 CFR 172.400**
 - 1. **49 CFR 172.400(a)** - General labeling requirements
 - 2. **49 CFR 172.403** - Radioactive materials [types and contents of labels]
 - 3. **49 CFR 172.406** - Placement of labels

- E. Placarding of Vehicles - **49 CFR 172.500**
 - 1. **49 CFR 172.504** - General placarding requirements
 - 2. **49 CFR 172.516** - Visibility and display of placards
 - 3. **49 CFR 172.556** - RADIOACTIVE placard

- F. Emergency Response Information - **Subpart G**
 - 1. **49 CFR 172.600** - Applicability and general requirements
 - 2. **49 CFR 172.602** - Emergency response information
 - 3. **49 CFR 172.604** - Emergency response telephone number

- G. Training - **Subpart H**
 - 1. **49 CFR 172.702** - Applicability and responsibility for training and testing [for HAZMAT employees]
 - 2. **49 CFR 172.702** - Training requirements (includes types of training, when it must be conducted, need for refresher training every 3 years, recordkeeping)

- H. Security Plans – **49 CFR 172**
 - 1. **49 CFR 172.800, 49 CFR 172.802**: Purpose and applicability, components of a security plan;

I. Shippers - General Requirements for Shipments and Packaging - 49 CFR 173

1. **49 CFR 173.25** - Requirements for use and labeling of overpacks
2. **49 CFR 173.403** - Definitions
3. **49 CFR 173.411** - General design requirements
4. **49 CFR 173.413** - Additional design requirements for Type B packages
5. **49 CFR 173.416** - Authorized Type B packages [includes packaging certification requirements]
6. **49 CFR 173.441** - Radiation levels
7. **49 CFR 173.471** - Additional requirements for Type B packages approved by NRC
8. **49 CFR 173.476** - Approval of special form radioactive materials [includes requirement for documentation of special form status]

J. Carriage by Public Highway - 49 CFR 177

1. **49 CFR 177.817** - Shipping paper [location of shipping papers during transport]
2. **49 CFR 177.842** - Class 7 (radioactive) material [includes requirement for blocking and bracing during transport]

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.

- Labeling is required to be: (1) placed near the required marking of the proper shipping name, (2) printed or affixed to the package surface, (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.
- Two labels are required on opposite sides of the package, excluding the bottom.

Determination of Required Label

Size: Sides: ≥ 100 mm Border: 5-6.3 mm			
	49 CFR 172.436	49 CFR 172.438	49 CFR 172.440
	WHITE-I	YELLOW-II	YELLOW-III
Required when:	Surface radiation level ≤ 0.005 mSv/hour (0.5 mrem/hour)	0.005 mSv/hour (0.5 mrem/hour) < surface radiation level ≤ 0.5 mSv/hour (50 mrem/hour)	0.5 mSv/hour (50 mrem/hour) < surface radiation level ≤ 2 mSv/hour (200 mrem/hour)
Or:	TI = 0 [1 meter dose rate < 0.5 mrem/hour]	TI ≤ 1 [1 meter dose rate ≤ 1 mrem/hour]	1 < TI ≤ 10 [1 meter dose rate ≤ 10 mrem/hour]

Content on Radioactive Labels

RADIOACTIVE label must contain (entered using a durable, weather-resistant means):

- (1) The radionuclides in the package. Symbols (e.g., Ir-192) 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.
- (3) The Transport Index (TI) in the supplied box. The TI is entered only on YELLOW-II and YELLOW-III labels.

Some Special Considerations for Labeling Requirements

- Radioactive material, excepted packages (e.g., Limited Quantity, Radioactive Instrument and Article) are excepted from labeling.
- The "Cargo Aircraft Only" label is typically required for radioactive materials packages shipped by air [§172.402(c)]

Marking Packages (49 CFR 172.300-308)

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.

Always Required, Unless Excepted	Sometimes Required	Optional
<ul style="list-style-type: none"> • Proper shipping name • U.N. Identification Number • Name and address of consignor or consignee, unless: <ul style="list-style-type: none"> -Highway only and no motor carrier transfers, or -Part of truckload lot and entire contents of freight container are shipped from one consignor to one consignee (§172.301(d)) 	<ul style="list-style-type: none"> • If in excess of 50 kg, Gross Weight • If hazardous substance, "RQ" in association with the proper shipping name • The package type if Type A or Type B (1/2" or greater letters) • The specification-required markings (see §178.350-353) • For approved packages, the certificate ID number 	<ul style="list-style-type: none"> • Both the name and address of consignor and consignee are recommended. • Other markings (e.g., advertising) are permitted, but must be sufficiently away from markings and labeling

Some Special Considerations for Marking Requirements

- Marking is required to be (1) durable, (2) printed on a package, label, tag, or sign, (3) unobscured by labels or attachments, (4) isolated from other marks, and (5) be representative of the hazmat contents of the package.
- Limited quantity packages (§173.421) must bear the marking "radioactive" on the outside of the inner package, or the outer package itself, and are excepted from other marking.
- Empty (§173.428) and Radioactive Instrument and Article (§173.424) packages are excepted from marking.

DOT Shipping Papers (49 CFR 172.200-205)

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

Always Required, Unless Excepted	Sometimes Required
<ul style="list-style-type: none"> • The basic description, in sequence <ul style="list-style-type: none"> Proper shipping name Hazard Class (7) U.N. Identification Number • 24 hour emergency response telephone number • Name of shipper • Proper page numbering (Page 1 of 4) • The total quantity (mass), in appropriate units • The name of each radionuclide and total package activity. The activity must be in SI units (e.g., Bq, TBq) or both SI units and customary units (e.g., Ci, mCi). • For each labeled package: <ul style="list-style-type: none"> - The category of label used - The transport index of each package with a Yellow-II or Yellow-III label - Shipper's certification (not required of private carriers) 	<ul style="list-style-type: none"> • If hazardous substance, "RQ" as part of the basic description
	<p align="center">Optional</p> <ul style="list-style-type: none"> • The type of packaging (e.g., Type B) • Other information is permitted (e.g., functional description of product), provided it does not confuse or detract from the proper shipping name or other required information • Emergency response hazards and guidance information (§§172.600-604) may be entered on the shipping papers, or may be carried with the shipping papers

Some Special Considerations/Exceptions for Shipping Paper Requirements

- Shipments of Radioactive Material, excepted packages, under UN2908-UN2911 (e.g., Limited Quantity, Empty, or Instrument and Article), are excepted from shipping papers. For limited quantities (§173.421), this is only true if the limited quantity is not a hazardous substance (RQ) or hazardous waste.
- Shipping papers must be in the pocket on the left door, or readily visible to a person entering the driver's compartment and within arm's reach of the driver.
- For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, be designated by an "X" (or "RQ") in the hazardous material column, or be highlighted in a contrasting color.

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

(Provide at least two copies to the airline.)

Shipper YOUR COMPANY NAME YOUR STREET ADDRESS CITY & STATE & ZIP CODE	Air Waybill No. Page 01 of 01 Pages Shipper's Reference Number RETURN <i>(optional)</i>
--	---

Consignee AEA TECHNOLOGY QSA 40 North Avenue Burlington MA 01803 U.S.A.	
--	--

Two completed and signed copies of this Declaration must be handed to the operator.

WARNING
 Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.

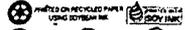
TRANSPORT DETAILS	
This shipment is within the limitations prescribed for: <i>(delete non-applicable)</i>	Airport of Departure
<input checked="" type="checkbox"/> PASSENGER AND CARGO <input type="checkbox"/> CARGO AIRCRAFT ONLY	
Airport of Destination:	

Shipment type: *(delete non-applicable)*
 ~~NON-FLAMMABLE~~ RADIOACTIVE

NATURE AND QUANTITY OF DANGEROUS GOODS						
Dangerous Goods Identification						
Proper Shipping Name	Class or Division	UN or ID No.	Packing Group	Subsidiary Risk	Quantity and Type of packing	Packing Inst. Authorization
RQ, RADIOACTIVE MATERIAL, TYPE B(U) PACKAGE,	7	UN2916			IR-192, Special Form 1 Type B(U) Package 1 X 925.0 GBq	II Special Form Cert USA/033548 ATTACHED YELLOW T.I. PACKAGE 0.5 Cert. USA/9269/ DIMS B(U)-96 26x22x34 ATTACHED CMS

Additional Handling Information **This shipment may be carried on passenger aircraft outside US jurisdiction.**
*** ICAO/IATA REGS USED ***
 YOUR 24 HR. NUMBER
 24 hr. Emergency Contact Tel. No.

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations.	Name/Title of Signatory YOUR NAME & TITLE Place and Date CITY & DATE Signature <i>(see warning above)</i>
---	--



2008F-UV

4

ATTENTION SHIPPERS! FREIGHT CHARGES ARE PREPAID ON THIS BILL OF LADING UNLESS MARKED COLLECT.

STRAIGHT BILL OF LADING

ORIGINAL - NOT NEGOTIABLE

Shipper No. _____

Carrier No. _____

Date **6/23/03**

Page **01** of **01**

(Name of carrier) (SCAC)

On Colored or Delivery shipments, the letters "COD" must appear before consignee's name or as otherwise provided in Item 430, Sec. 1.

TO: **AEA TECHNOLOGY QSA**
 Consignee
 Street **40 NORTH AVENUE**
 City **BURLINGTON MA** State Zip Code **01803**

FROM: **YOUR COMPANY NAME**
 Shipper
 Street **YOUR STREET ADDRESS**
 City **CITY** State **STATE** Zip Code **ZIP CODE**
YOUR 24 HOUR EMERGENCY NUMBER
 24 hr. Emergency Contact Tel. No. _____

Route	No. of Units & Container Type	HM	BASIC DESCRIPTION Proper Shipping Name, Hazard Class, Identification Number (UN or NA), Packing Group, per 172.101, 172.202, 172.203	TOTAL QUANTITY (Weight, Volume, Gallons, etc.)	WEIGHT (Subject to Correction)	RATE	CHARGES (For Carrier Use Only)
	01		MODEL 650L CONTAINING: RQ RADIOACTIVE MATERIAL TYPE B(U) PACKAGE, CLASS 7, UN2916 Special Form, IR-192 925.0 GBq T.I. 0.5 USA/9269/B(U)-96 TYPE B Yellow II Labels Attached	01	80 LBS	CL100	

PLACARDS TENDERED: YES NO

REMIT C.O.D. TO ADDRESS: **COD** Amt: \$ _____

Signature _____

Signature of Consignor _____

Signature of Carrier _____

Signature of Shipper _____

Signature of Consignee _____

SHIPPER **YOUR COMPANY NAME**

PER **YOUR NAME & TITLE**

CARRIER _____

PER _____

DATE _____

HAZARDOUS MATERIAL SHIPPING CERTIFICATION				
FOR COMPANY VEHICLE TRANSPORTING IRIIDIUM 192 SEALED SOURCES				
SHIPPER* Mo-Rad, Inc. 1234 Main Street Anywhere, USA 20000			CONSIGNEE* Mo-Rad, Inc. 1234 Main Street Anywhere, USA 20000	
DATE*		NUMBER OF TERABEQUERELS (CURIES)	TRANSPORT* INDEX (MR/HR @ 39.37")	CERTIFYING* SIGNATURE
5/01/98	Metal Fabricators 4321 Broad Street Somewhere, USA	1.9 (50)	0.4	John Jones
DESCRIPTION OF PIECES AND CONTENTS				
RQ RADIOACTIVE MATERIAL - SPECIAL FORM N.O.S. - UN 2974 - CLASS 7 IRIIDIUM 192: 110 CURIES MAXIMUM TYPE B CONTAINER - YELLOW LABEL II - TRANSPORT INDEX NOT TO EXCEED 1.0				
AMERSHAM MODEL 680 SERIES <input type="checkbox"/> USA/9033/B(U)	AMERSHAM SHIP/CON MODEL 650L <input type="checkbox"/> USA/9269/B(U)	SPEC MODEL 150 <input type="checkbox"/> USA/9263/B(U)	SPEC SHIP/CON MODEL C-1 <input type="checkbox"/> USA/9036/B(U)	
<i>This is to certify that the above named materials are properly classified, described, packaged, marked, labeled and are in proper condition for transportation according to the applicable regulations of the DEPARTMENT OF TRANSPORTATION . (See certifying signature above)</i>				
INSTRUCTIONS				
"Radioactive Yellow II Label" - 0.5 to 50 mR/hr on the surface of package and not over 1.0 mR/hr at 39.37" from container. Yellow II label does not require vehicle placards. NOTE: Do not transport if surface of container is over 50 mR/hr and/or over 1 mR/hr at 39.37" from container.				
Shipping papers must be within reach of the driver when wearing a seat belt. Should the driver leave the vehicle, the shipping papers are to be left on the front seat of the driver's side or in a box on the driver's side of the vehicle.				
If a motor vehicle accident occurs, it is required that an accident report be filed with the DOT within 15 days. Give no information regarding radioactive material to anyone present at the scene except police or DOT or NRC officials. Other information is to be obtained from the Radiation Safety Officer				
EMERGENCY TELEPHONE NUMBER - 1-800-000-0000				

* Substitute appropriate information for your device and shipment.

Appendix O

Daily Maintenance Check of Radiographic Equipment

Daily Maintenance Check of Radiographic Equipment

A. The radiographer or radiographer's assistant shall perform a daily maintenance check of the exposure device and related radiographic equipment. This inspection will be performed before using the equipment on each day the equipment is to be used. Report defective equipment to the RSO immediately. Do not attempt to use defective equipment. After the inspection, document the results of the inspection.

1. Inspect the survey meter for battery check, zero and operation. If batteries are low, replace, then check for operability. If not able to correct a problem with the survey meter, obtain another meter and start over.

2. Check survey meter with a check source (which should give a reading of _____ millirem) (or check with camera _____ which should give a reading of _____ millirem) as indicated on the survey meter. If reading is not acceptable, obtain another meter and start again.

Note: RSO or calibration vendor should determine the acceptable meter reading for each survey meter and post the expected reading on each instrument. This reading shall be obtained and noted at the time of calibration.

3. Inspect the remote-control radiographic equipment as follows:

- Inspect the cables for cuts, breaks, and broken fittings.
- Carefully inspect approximately one foot of the drive cable immediately next to the male connector. Take care not to introduce any dirt or dust on the drive cable during this inspection. In addition to the previously mentioned items, the examination of the cable should look for any of the following:
 - Excessive or uneven wearing;
 - Fraying;
 - Unraveling;
 - Nicks;
 - Kinks or bends;
 - Loss of flexibility (abnormal stiffness);
 - Excessive grit or dirt;
 - Stretching;
 - Inspect the crank unit for damage and loose hardware;
 - Check operation of the control for freedom of drive cable movement;
 - Inspect the guide tube for cuts, crimps, and broken fittings;
 - Survey for radiation levels and record readings. The radiation levels should be about the same as those in the previous day's inspection, unless there has been a source change;
 - Check that all safety plugs are in place;
 - Inspect the exposure device for damage to fittings, lock, fasteners, and labels; and
 - Check for any impairment of the locking mechanism.

4. Record the results of the daily inspection.

Appendix P
Model Emergency Procedure

Model Emergency Procedure

If the source fails to return to the shielded position or if any other emergency or unusual situation arises (e.g., vehicle accident, off-scale dosimeter, etc.)

- Immediately secure the area and post the restricted area at the 0.02 mSv/hr (2 mrem/hr) radiation level; maintain continuous surveillance and restrict access to the restricted area.
- Notify the RSO and/or Management Personnel.
- Take no further actions until instructions are received from the RSO.
- Do not attempt source retrieval until the situation has been discussed with the RSO or other knowledgeable personnel.
- Don't panic. Source retrieval can be performed with very little exposure when properly planned by trained personnel.
- Notify the persons listed below of the situation, in the order shown.

Name*	Work Phone Number*	Home Phone Number*

* Fill in with (and update, as needed) the names and telephone numbers of appropriate personnel (e.g., the Radiation Safety Officer (RSO), or other knowledgeable licensee staff, licensee's consultant, device manufacturer) to be contacted in case of emergency. Update information as necessary.

Follow the directions provided by the person contacted above.

RSO and Licensee Management

Discuss emergency operating procedures, and ensure no operations are conducted until the situation has been discussed with and approved by the RSO or other knowledgeable staff, consultants, or device manufacture. Management should have access to emergency equipment to keep doses to radiographers ALARA. Emergency equipment may include high range dosimeters, extra lead shielding, remote tongs, etc.

Notify local authorities as well as the agency as required. The agency notification is required when sources or devices containing licensed material are lost or stolen and when radiographic sources or equipment are involved in incidents that may have cause or threatens to cause an exposure in excess of 12VAC5-481-1100 limits. Reports to the agency must be made within the reporting time frames specified by 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, and 12VAC5-481-1120.

Telephone notifications shall be made to the agency at (804) 864-8150 during normal business hours (8 a.m. – 4:30 p.m.). For immediate notifications after normal business hours, the agency's 24 hour emergency telephone number is (804) 674-2400 or (800) 468-8892. Identify the emergency as radiological.

Commonwealth of Virginia Radiation Protection Regulatory Guide



Guidance for Fixed Gauge Devices

EPI-720 C

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

EXECUTIVE SUMMARY

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

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

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

<http://www.vdh.virginia.gov/Epidemiology/RadiologicalHealth/>.

This VAREG, ‘Guidance for Fixed Gauge Devices’ has been developed to streamline the application process for a Fixed Gauge License. A copy of the VDH Form, ‘Application for Radioactive Material License Authorizing the Use of Sealed Sources in Fixed Gauge Devices’ is located in **Appendix A** of this guide.

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

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

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

- Use this regulatory guide to prepare the VDH Form, 'Application for Radioactive Material License Authorizing the Use of Sealed Sources in Fixed Gauge Devices' (**Appendix A**).
- Complete VDH Form, 'Application for Radioactive Material License Authorizing the Use of Sealed Sources in Fixed Gauge Devices' (**Appendix A**). See "Contents of Application" of the guide for additional information.

- Include any additional attachments.

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

Please identify all attachments with the applicant's name and license number (if a renewal).

- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original signed application along with attachments (if any).
- Submit the application fee (for new licenses only).
- Retain one copy of the license application and attachments (if any) for your future reference. You will need this information because the license will require that radioactive material be possessed and used in accordance with statements, representation, and procedures provided in the application and supporting documentation.

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

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ABBREVIATIONS

ALARA	as low as is reasonably achievable
ALI	annual limit on intake
bkg	background
Bq	Becquerel
CFR	Code of Federal Regulations
Ci	Curie
cc	centimeter cubed
cm ²	centimeter squared
cpm	counts per minute
DOT	United States Department of Transportation
dpm	disintegrations per minute
GM	Geiger-Mueller
IN	Information Notice
mCi	millicurie
mR	milliroentgen
mrem	millirem
mSv	millisievert
NIST	National Institute of Standards and Technology
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OSL	optically stimulated luminescence dosimeters
RG	Regulatory Guide
RSO	Radiation Safety Officer
SI	International System of Units (abbreviated SI from the French Le Système Internationale d'Unites)
SSDR	Sealed Source and Device Registration
Sv	Sievert
TEDE	total effective dose equivalent
TLD	thermoluminescent dosimeters
VDH	Virginia Department of Health
μCi	microcurie
%	percent

PURPOSE OF GUIDE

This document provides guidance to an applicant in preparing a license application for a Fixed Gauge License. It also provides guidance on VDH's criteria for evaluating a Fixed Gauge license application. It is not intended to address the commercial aspects of manufacturing, distribution, and service of sources in devices. Various designs of fixed gauges are based in part on their intended use and the location of the radioactive source within the gauge. Typically gauges are used for process control (e.g., to measure the thickness of paper, the density of coal, the level of material in vessels and tanks, and volumetric flow rate). Because of differences in design, manufacturers provide appropriate instructions and recommendations for proper operation and maintenance. In addition, with gauges of varying designs, the sealed sources may be oriented in different locations within the devices, resulting in different radiation safety considerations.

This guide describes the information needed to complete VDH Form, 'Application for Radioactive Material License Authorizing the Use of Sealed Sources in Fixed Gauge Devices' (**Appendix A**).

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

- **Rule** – references the requirements of 12VAC5-481 'Virginia Radiation Protection Regulations' applicable to the item;
- **Criteria** – outlines the criteria used to judge the adequacy of the applicant's response;
- **Discussion** – provides additional information on the topic sufficient to meet the needs of most readers; and
- **Response from Applicant** – shows the appropriate item on the application and provides: response(s), offers the option of an alternative response, or indicates that no response is needed on that topic.

The information submitted in the application must be sufficient to demonstrate that proposed equipment, facilities, personnel, and procedures are adequate to protect the health and safety of the citizens of the Commonwealth of Virginia in accordance with agency guidelines.

Submission of incomplete or inadequate information will result in delays in the approval process for the license. Additional information will be requested when necessary to ensure that an

adequate radiation safety program has been established. Such requests for additional information will delay completion of the application's review and may be avoided by a thorough study of the rule and these instructions prior to submitting the application:

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

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

This VAREG provides the latest guidance and is modeled on the Nuclear Regulatory Commission's (NRC) NUREG 1556, Volume 4. The VAREG shows the requirements in terms of the **12VAC5-481 'Virginia Radiation Protection Regulations'** and provides a user-friendly format to assist with the preparation of a Fixed Gauge Device license application.

LICENSES

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

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

- Statements, representations, and procedures contained in the application and in correspondence with VDH;
- Terms and conditions of the license; and
- **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 regulatory authority.

Table 1: Who Regulates the Activity?

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

Note: 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 RESPONSIBILITIES

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

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

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

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

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

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 Fixed Gauge licensees:

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

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

<http://www.vdh.virginia.gov/Epidemiology/RadiologicalHealth/>.

HOW TO FILE

Applicants for a materials license should do the following:

- Be sure to use the current guidance from VDH in preparing an application.
- Complete VDH Form, 'Application for Radioactive Material License Authorizing the Use of Sealed Sources in Fixed Gauge Devices' (**Appendix A**).
- For each separate sheet, other than submitted with the application, identify and key it to the item number on the application, or the topic to which it refers.
- Submit all documents on 8 ½ x 11 inch paper.
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original, signed application.
- Retain one copy of the license application for your future reference.

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

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

WHERE TO FILE

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

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

LICENSE FEES

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

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

Direct all questions about VDH's fees or completion of **Item 11** of VDH Form, 'Application for Radioactive Material License Authorizing the Use of Sealed Sources in Fixed Gauge Devices' (**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: License Action Type

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

Response from Applicant:

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

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. Notify the agency of changes in mailing address.

Response from Applicant:

<p>Item 2 Name and Mailing Address of Applicant</p> <hr/> <p>Applicant's Telephone Number (Include area code)</p>
--

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

Timely Notification of Change of Ownership or Control

Rule: 12VAC5-481-330, 12VAC5-481-500 B

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

Discussion: Changes in ownership may be the result of mergers, buyouts, or majority stock transfers. Although it is not the agency's intent to interfere with the business decisions of

licensee's, it is necessary for licensees to obtain the agency's prior written consent. This is to ensure the following:

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

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

Notification of Bankruptcy Proceedings

Rule: 12VAC5-481-500 E & F

Criteria: Immediately following filing of voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify VDH, in writing, identifying the bankruptcy court in which the petition was filed and the date of filing.

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

Item 3: Person to Be Contacted Regarding Application

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

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

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

Response from Applicant:

Item 3 Person to Contact Regarding Application
Contact Person - Telephone Number (Include area code)

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

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

Criteria: Most applicants need to provide two types of information in response to Item 4:

- Description of storage, use, and dispatch locations
- Specification of whether they intend to use the fixed gauge at temporary job sites.

Discussion: Specify the street address, city and state or other descriptive address (such as on Highway 58, 5 miles east of the intersection of Highway 58 and State Route 19, Anytown, VA, Zip) for each permanent facility used as a location of storage or use, and each facility from which the applicant will dispatch gauge users to job sites for more than one customer. 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.**

Obtaining a VDH license does not relieve a licensee from complying with other applicable federal, state, or local regulations (e.g., local zoning requirements for storage locations).
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To conduct operations at temporary jobsites (i.e., locations where work is conducted for limited periods of time and from which gauge users are NOT dispatched to jobsites for other customers), specify "*temporary job sites anywhere in Virginia where VDH maintains jurisdiction*".

A VDH license amendment is required before locating a gauge at an address not already listed on the license, whether that gauge is an additional unit or a relocation of an existing unit.

For information on conducting operations at temporary job sites (i.e., locations where work is conducted for limited periods of time), refer to the section in this report called 'Fixed Gauges Used at Temporary Job Sites'. That section offers examples of operations where fixed gauges might be used at temporary job sites and gives information that should be provided to the agency to support a request for these operations.

Response from the applicant:

Item 4. Address(es) Where Radioactive Material Will Be Used Or Possessed (Do not use Post Office Box)	
Address	Telephone Number (Include Area Code)
Address	Telephone Number (Include Area Code)
Address	Telephone Number (Include Area Code)

Note: As discussed later in the section 'Financial Assurance and Record Keeping for Decommissioning', licensees do need to maintain permanent records on where licensed material was used or stored while the license was in force. This is important for making future determinations about the release of these

locations for unrestricted use (e.g., before the license is terminated). For fixed gauge licensees, acceptable records are sketches or written descriptions of specific locations where each gauge was used or stored and any information relevant to damaged devices or leaking radiation sources.

Item 5: Radiation Safety Officer (RSO)

Rule: 12VAC5-481-450 A, 12VAC5-481-630

Criteria: Radiation Safety Officers (RSOs) must have adequate training and experience. Successful completion of training of one of the following is evidence of adequate training and experience:

- Fixed gauge manufacturer's or distributor's course for users or for RSO's
- Equivalent course that meets **Appendix G** criteria

Additional training is required for RSOs of programs that perform non-routine operations. This includes repairs involving or potentially affecting components related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding) and any other activities during which personnel could receive radiation doses exceeding VDH limits (e.g., installation, initial radiation survey, gauge relocation, and removal of the gauge from service). See 'Radiation Safety Program – Maintenance' in this report and **Appendix N**.

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

Response from Applicant:

Item 5. Radiation Safety Officer (RSO) (Check one box and attach evidence of training and experience)	
Name: _____	Telephone Number (Include area code): (_____) _____ - _____ X _____
<input type="checkbox"/> Before obtaining radioactive material, the proposed RSO will have successfully completed one of the training courses described in Criteria in the section titled 'Radiation Safety Officer (RSO)' in VAREG 'Guidance For Fixed Gauge Devices'. Before being named as the RSO, future RSOs will have successfully completed one of the training courses described in Criteria in the section titled 'Radiation Safety Officer (RSO)' in VAREG 'Guidance For Fixed Gauge Devices'.	
OR	
<input type="checkbox"/> Alternative information demonstrating that the proposed RSO is qualified by training and experience is attached. Before being named as the RSO, future RSOs will have successfully completed one of the training courses described in Criteria in the section titled 'Radiation Safety Officer (RSO)' in VAREG 'Guidance For Fixed Gauge Devices'.	

Note:

- It is important to notify the agency as soon as possible, of changes in the designation of the RSO;
- Alternative responses will be evaluated using the criteria listed above.

Item 6: Authorized Users - Training for Individuals Working In or Frequenting Restricted Areas

Rule: 12VAC5-481-450 A, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-2260, 12VAC5-481-2270, 12VAC5-481-2280, 12VAC5-481-2310

Criteria: Authorized users (AUs) must have adequate training and experience. Successful completion of one of the following is evidence of adequate training and experience:

- Fixed gauge manufacturer's or distributors course for users
- Equivalent course that meets **Appendix G** criteria

Applicants requesting to perform non-routine operations such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement and disposal of sealed sources, alignment, or removal of a gauge from service, must provide additional training. See the section in this report entitled 'Radiation Safety Program – Maintenance' and **Appendix N**.

Discussion: An AU is a person whose training and experience meet the agency's criteria, who is named either explicitly or implicitly on the license, and who uses or directly supervises the use of licensed material. AUs must ensure the proper use, security, and routine maintenance of fixed gauges containing licensed material. AUs must attend the training and instruction given at the time of installation or receive equivalent training and instruction.

An AU is considered to be supervising the use of licensed material when he or she directs personnel in operations involving the material. Although the AU may delegate specific tasks to supervised users (e.g., maintaining records), he or she is still responsible for safe use of licensed material.

Response from Applicant:

<p>Item 6. Training For Individuals Working In Or Frequenting Restricted Areas (Check one box)</p> <p><input type="checkbox"/> Before using radioactive material, authorized users will have successfully completed one of the training courses described in Criteria in the section titled 'Training for Individuals Working In or Frequenting Restricted Areas' in VAREG 'Guidance For Fixed Gauge Devices'.</p> <p>NOTE: If using in-house training program, submit copies of course content, sample course examination, and course instructor qualifications.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> Documentation of the training and experience for the proposed gauge user(s) is/are attached.</p>
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Note: Records of training should be maintained. Alternative responses will be evaluated against the criteria listed above.

Item 7: Radioactive Material and Item and Item 8: Intended Use

Part 1: Sealed Sources and Devices

Rule: 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-630, 12VAC5-481-720

Criteria: Applicants must provide the manufacturer's or distributor's name and model number for each requested sealed source and device. Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by the NRC or another Agreement State.

Discussion: NRC or another Agreement State performs a safety evaluation of fixed gauges before authorizing a manufacturer or distributor to distribute the gauges to specific licensees. The safety evaluation is documented in a Sealed Source and Device Registration (SSRD) Certificate. Before the SSDR process was formalized, some older gauges may not have been evaluated in a separate document, but were specifically approved on a license. Licensees can continue to use these gauges that are specifically listed on their licenses.

Consult with the proposed manufacturer or distributor to ensure that sources and devices conform to the sealed source and device designations registered with NRC or another Agreement State. Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective registration certificates, without obtaining the agency's prior permission in a license amendment. Such changes may necessitate a custom registration review, increasing the time needed to process a licensing action.

SSDR Certificates contain sections on "*Conditions of Normal Use*" and "*Limitation and Other Considerations of Use*". These sections may include limitations derived from conditions imposed by the manufacturer or distributor, by particular conditions of use that would reduce radiation safety of the device, or by circumstances unique to the sealed source or device. 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 SSDR 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.

Response from Applicant:

Item 7. Radioactive Material (Attach additional pages if necessary)			
Element And Mass Number	<input type="checkbox"/> Cobalt-60	<input type="checkbox"/> Krypton-85	<input type="checkbox"/> Americium-241
	<input type="checkbox"/> Cesium-137	<input type="checkbox"/> Strontium-90	<input type="checkbox"/> Radium-226
	<input type="checkbox"/> Other Isotope (Please specify) _____		
List name of Sealed Source Manufacturer or Distributor and Model Number		List Name of Device Manufacturer or Distributor and Model Number	
Item 8. Intended Use			
Maximum Quantity (Not to exceed either the maximum activity per source or device as specified in the Sealed Source and Device Registration Certificate)		Intended use	

Note: SDR certificates include reviews by the NRC and other Agreement States. Contact the agency at (804) 864-8150 for assistance with locating specific SDR certificates.

Part 2: Financial Assurance and Recordkeeping for Decommissioning

Rule: 12VAC5-481-100, 12VAC5-481-450 C, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-1161

Criteria: Fixed gauge licensees authorized to possess sealed sources containing radioactive material in excess of the limits specified in 12VAC5-481-450 C must provide evidence of financial assurance for decommissioning.

Even if no financial assurance is required, licensees are required to maintain, in an identified location, decommissioning records related to structures, equipment, locations where gauges are used or stored, and leaking sources. Pursuant to 12VAC5-481-450 C, licensees must transfer these records important to decommissioning to either of the following:

- The new licensee before licensed activities are transferred or assigned according to 12VAC5-481-500 B.
- The agency before the license is terminated.

Discussion: The requirements for financial assurance are specific to the types and quantities of radioactive material authorized on a license. Most fixed gauge applicants and licensees do not need to take any action to comply with the financial assurance requirements because their total inventory of licensed material does not exceed the thresholds in 12VAC5-481-450 C. The thresholds for typical radionuclides used for fixed gauge sealed sources are shown in Table 2.

Table 2. Examples of Minimum Inventory Quantities Requiring Financial Assurance

Radionuclide (Sealed Sources)	Activity in Gigabecquerels	Activity in Curies
Co-60	3.7×10^5	10,000
Kr-85	3.7×10^7	1,000,000
Sr-90	3.7×10^4	1,000
Cs-137	3.7×10^6	100,000
Am-241	3.7×10^3	100
Ra-226	3.7×10^3	100
Cf-252	3.7×10^3	100

A licensee would need to possess hundreds of gauges before the financial assurance requirements would apply. Since the standard gauge license does not specify the maximum number of gauges that a licensee may possess (allowing flexibility in obtaining additional gauges specifically authorized by the license as needed without amending its license), it contains a condition requiring the licensee to limit its possession of fixed gauges to quantities not requiring financial assurance. Applicants and licensees desiring to possess gauges exceeding the threshold amounts must submit evidence of financial assurance.

Applicants requesting more than one radionuclide may determine whether financial assurance for decommissioning is required by calculating, for each radionuclide 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 regulation also requires that licensees maintain records important to decommissioning in an identified location. All fixed gauge licensees need to maintain records of structures and equipment where each gauge 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 gauges 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 fixed gauge licensees have experienced unusual occurrences (e.g., leaking sources, other incidents that involve spread of contamination), they also need to maintain records about contamination that remains after cleanup or that may have spread to inaccessible areas.

For fixed gauge licensees whose sources have never leaked, acceptable records important to decommissioning are sketches or written descriptions of the specific locations where each gauge was used or stored.

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 B** or to the agency before the license is terminated.

Reference: NRC Regulatory Guide 3.66 "*Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70 and 72*", is available from the agency upon request.

Part 3: Purpose(s) for Which Licensed Material Will Be Used

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

Criteria: Proposed activity is authorized by 12VAC5-481 'Virginia Radiation Protection Regulations'. Gauges should be used only for the purposes for which they were designed, according to the manufacturer's or distributor's recommendations and instructions, as specified in an approved SSDR Certificate, and as authorized on a VDH license.

Discussion: Uses other than those listed in the SSDR Certificate require review and approval by the agency, the NRC or another Agreement State. Requests to use fixed gauges for purposes not listed in the SSDR Certificate will be reviewed on a case-by-case basis. Applicants need to submit sufficient information to demonstrate that the proposed use will not compromise the integrity of the source or source shielding, or other radiation safety-critical components of the device. The agency will evaluate the radiation safety program for each type and use of gauge requested.

Note:

- A VDH license does not relieve a licensee from complying with other applicable federal, state, or local regulations.
- Allowed uses of fixed gauges normally include process control methods such as measuring the thickness of paper, the density of coal, the level of material in vessels and tanks, etc.
- Unusual uses will be evaluated on a case-by-case basis and the authorized use condition will reflect approved uses.
- If the applicant wishes to be authorized for fixed gauge use at temporary jobsites (see **Item 10.12**) indicate in purpose of use.

Item 9: Facilities and Equipment

Rule: 12VAC5-481-450 A, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-840, 12VAC5-481-850, 12VAC5-481-860, 12VAC5-481-880

Criteria: Facilities and equipment must be adequate to protect health and to minimize danger to life or property. This may be demonstrated by the following:

- The location of the gauge is compatible with the "*Conditions of Normal Use*" and "*Limitations and/or Other Considerations of Use*" on the SSDR Certificate
- The fixed gauge is secured to prevent unauthorized removal or access (e.g., located in a locked room, permanently mounted, or chained and locked to a storage rack).

Discussion: Fixed gauges incorporate many engineering features to protect the user from unnecessary radiation exposure in a wide variety of environments. Fixed gauges may be located in harsh environments involving variables such as pressure, vibration, mounting height/method, temperature, humidity, air quality, corrosive atmospheres, corrosive chemicals including process materials and cleaning agents, possible impact or puncture conditions, and fire, explosion, and flooding potentials. Applicants need to consult the sections on the SSDR Certificate entitled, "*Conditions of Normal Use*" and "*Limitations and/or Other Considerations of Use*" to determine the appropriate gauge for a location. In those instances when a proposed location is not consistent with the SSDR Certificate, the applicant may ask the source or device manufacturer or distributor to request an amendment to modify the SSDR Certificate to include the new

conditions. If the manufacturer or distributor does not request an amendment, the applicant must provide the agency with specific information demonstrating that the proposed new conditions will not impact the safety or integrity of the source or device.

12VAC5-481-450 A states that an application will be approved if, among other things, the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to the public's health and safety. **12VAC5-481-840** states that (1) sources of radiation shall be secured against unauthorized removal from the place of storage and (2) sources of radiation in an unrestricted area and not in storage shall be tended under the constant surveillance and immediate control of the licensee or registrant.

You should keep in mind that the device needs to be in storage or physically watched by authorized users at all times. It is not acceptable for a device to be chained to a post or left lying unattended at the place of use during lunch or breaks, because the device would then be accessible to unauthorized persons.

Response from Applicant:

<p>Item 9. Facilities And Equipment (Check boxes and attach diagram)</p> <p><input type="checkbox"/> Diagrams of radioactive material area(s) of use are attached.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> The fixed gauge is secured to prevent unauthorized removal or access and these security features will not impact the safety or integrity of the source or device.</p>
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Note:

- Any deviations from an SSDR Certificate will require specific agency approval.
- Alternative responses will be evaluated using the criteria listed above.

References: Information Notices are available in the "Reference Library" on NRC's Home Page at <http://www.nrc.gov/>. SSDR certificates include reviews by the NRC and other Agreement States. If necessary, contact the agency for assistance with locating specific SSDR certificates.

Item 10: Radiation Safety Program

Item 10.1: Audit Program

Rule: 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-630, 12VAC5-481-980, 12VAC5-481-990

Criteria: Licensees must review the content and implementation of their radiation protection programs at intervals not to exceed 12 months 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 H contains a suggested audit program that is specific to the use of fixed gauges and is acceptable to the agency. All areas indicated in Appendix H may not be applicable

to every licensee and all items may not need to be addressed during each audit. For example, licensees do not need to address areas, which do not apply to their activities, and activities, which have not occurred since the last audit need not be reviewed at the next audit. Currently the agency's emphasis in inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of fixed gauge users to determine if, for example, operating and emergency procedures are available and 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 will normally 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.

Licensees must maintain records of audits and other reviews of program content and implementation for 3 years from the date of the record. The agency has found audit records that contain the following information to be acceptable: date of audit, name of person(s) who conducted audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up.

Response from Applicant:

Item 10.1 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.

References: Information Notices (i.e., IN 96-28) are available in the "*Reference Library*" on NRC's Home Page at <http://www.nrc.gov>.

Item 10.2: Termination of Activities

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-1161

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

- Notify the agency, in writing, within 60 days of:
 - Expiration of the license.
 - Decision to permanently cease licensed activities at the entire site or in any separate building or outdoor area that contains residual radioactivity making them unsuitable for release according to VDH requirements.
 - No principal activities having been conducted at the entire site under the license for a period of 24 months.

- No principal activities having been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity making them unsuitable for release according to VDH requirements.
- Submit decommissioning plan, if required by **12VAC5-481-510**.
- Conduct decommissioning, as required by **12VAC5-481-510 & 12VAC5-481-1161**.
- Submit, to the agency a completed VDH Form, 'Certificate for Disposition of Material' (or equivalent information) and a demonstration that the premises are suitable for release for unrestricted use (e.g., results of final survey).
- Before a license is terminated, send the records important to decommissioning to VDH. If licensed activities are transferred or assigned in accordance with **12VAC5-481-500 B**, transfer records important to decommissioning to the new licensee.

Discussion: As noted in several instances discussed in above, before a licensee can decide whether it must notify the agency, the licensee must determine whether residual radioactivity is present and if so, whether the levels make the building or outdoor area unsuitable for release according to VDH requirements. A licensee's determination that a facility is not contaminated is subject to verification by an agency inspection.

For guidance on the disposition of radioactive material, see the section on 'Waste Management - Gauge Disposal or Transfer'. For guidance on decommissioning records, see the section on 'Radioactive Materials – Financial Assurance and Record Keeping for Decommissioning'.

Item 10.2 Termination Of Activities

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

Item 10.3: Survey Instruments and Instrument Calibration

Rule: **12VAC5-481-450 A, 12VAC5-481-490 B, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-720, 12VAC5-481-750, 12VAC5-481-1000**

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

Discussion: Usually it is not necessary for fixed gauge licensees to possess a survey meter. However, surveys according to **12VAC5-481-750** will be required if an applicant plans to conduct non-routine operations. This includes installation, initial radiation surveys, relocation, removal from service, dismantling, alignment, replacement, disposal of the sealed source, and non-routine maintenance and repair of components related to the radiological safety of the gauge. Because some of these operations may increase the risk of radiation exposure, individuals performing these operations should be carefully monitored with a survey meter. Such survey meters should be properly calibrated. Proper calibration is particularly important for initial surveys since the results can be used as a basis for public dose estimates.

For those licensees requesting authorization to calibrate their own survey instruments, **Appendix I** contains calibration procedures acceptable to the agency. Licensees who perform surveys pursuant **12VAC5-481-750** must possess a survey meter that:

- Measures at least 0.3 through 200 mR per hour (50 microcoulombs per kilogram)
- Is capable of measuring the radiation being emitted from the gauge's sealed source

- Is checked for functionality with a source of radiation at the beginning of each day of use (e.g., with the gauge or a check source)
- Is calibrated:
 - At intervals not to exceed 12 months
 - Using a source of radiation similar to those found in the gauges
 - To ensure that exposure rates indicated by the meter do not vary from the actual exposure rates by more than $\pm 20\%$ on each scale
 - After any servicing or repair (other than a simple battery exchange)
 - By the instrument manufacturer or person specifically authorized by VDH, the NRC or an Agreement State.

Since many fixed gauge licensees are not required to possess a survey meter, applicants should preplan how they will obtain assistance in performing a radiation survey in the event of an emergency (e.g., obtain a survey instrument from hospitals, universities, other VDH, NRC or another Agreement State licensees, or local emergency response organization). It is important to determine as soon as possible after an incident, by the use of a radiation survey meter, whether the shielding and source are intact.

For those licensees using gauges containing only beta, neutron or alpha-emitting radionuclides, specialized survey instruments may be required.

Response from Applicant:

<p>Item 10.3 Survey Instruments and Instrument Calibration (Check one box)</p> <p><input type="checkbox"/> We will have access to and use, a radiation survey meter that meets the Criteria in the section titled 'Survey Instruments' in VAREG 'Guidance for Fixed Gauge Devices'. (Description attached)</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will possess a radiation survey meter that meets the Criteria in the section entitled 'Survey Instruments' in VAREG 'Guidance for Fixed Gauge Devices'.</p> <p style="text-align: center;">AND ONE OF THE FOLLOWING</p> <p><input type="checkbox"/> Each survey meter will be calibrated by an organization licensed by VDH, the NRC or another Agreement State to perform survey meter calibrations.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will implement the model survey meter calibration program published in Appendix I in VAREG 'Guidance for Fixed Gauge Devices'.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will submit alternative calibration procedures for agency review. (Procedures are attached)</p>

Note:

- Surveys according to **12VAC5-481-750** will be performed by a person specifically authorized by VDH, the NRC or another Agreement State to perform these surveys.
- Alternative responses will be reviewed against the criteria listed above.
- The VDH license will state that the instrument manufacturer will perform survey meter calibrations or a person specifically authorized by VDH, the NRC or another Agreement State, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey meter calibrations must submit additional information for review. See **Appendix I** for more information.
- Regardless of whether an applicant is authorized to calibrate survey meters or contracts an authorized firm to perform calibrations, the licensee must retain calibration records for at least 3 years.

Item 10.4: Material Receipt and Accountability

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-490 B, 12VAC5-481-500, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-900, 12VAC5-481-980, 12VAC5-481-1090, 12VAC5-481-3091, 12VAC5-481-3100

Criteria: Licensees must do the following: Maintain records of receipt, transfer, and disposal of fixed gauges and conduct physical inventories at intervals not to exceed 6 months, or some other interval justified by the applicant and approved by the agency, to account for all sealed sources.

Discussion: Radioactive materials must be tracked from 'cradle to grave' in order to ensure gauge accountability, identify when gauges could be lost, stolen, or misplaced, and ensure that possession limits listed on the license are not exceeded and the licensee complies with financial assurance requirements in 12VAC5-481-450 C. Licensees must maintain records of receipt, transfer, and disposal and conduct semiannual physical inventories. Significant problems can arise from failure to ensure the accountability of gauges. See Information Notice 88-02, "Lost or Stolen Gauges", dated February 2, 1988.

'Cradle to Grave' accountability refers to maintaining the radioactive material from the moment it becomes a part of your organization 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).

Receipt, transfer, and disposal records must be maintained for the times specified in **Table 3**. Typically, these records contain the following types of information:

- Radionuclide and activity (in units of becquerels or curies) of radioactive material in each sealed source
- Manufacturer's or distributor's name, model number, and serial number (if appropriate) of each device containing radioactive material
- Location of each sealed source and device
- 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).

Table 3. Record Maintenance

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

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 the section on 'Financial Assurance and Record Keeping for Decommissioning' for additional information.

Response from Applicant:

Item 10.4 Material Receipt and Accountability (Check one box)

Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license.

OR

We will submit a description of the frequency and procedures for ensuring that no gauge has been lost, stolen or misplaced. (Procedures are attached)

References: Information Notices (i.e. IN 88-02) are available on the NRC's Home Page at <http://www.nrc.gov>

Item 10.5: Occupational Dosimetry

Rule: 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-700, 12VAC5-481-710, 12VAC5-481-750, 12VAC5-481-760, 12VAC5-481-770, 12VAC5-481-1040, 12VAC5-481-1130, 12VAC5-481-1140, 12VAC5-481-2280

Criteria: Applicants must do either of the following:

- 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 (5 Rem TEDE) pursuant to **12VAC5-481-640**.

OR

- 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.

Discussion: Under conditions of routine use, the typical fixed gauge user does not require a personnel monitoring device (dosimetry). A gauge user also does not require dosimetry when proper emergency procedures are used. **Appendix J** provides guidance on performing a prospective evaluation demonstrating that fixed gauge users are not likely to exceed 10% of the limits as shown in **Table 4** and thus, are not required to have personnel dosimetry.

Individuals who perform non-routine operations such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement, and disposal of sealed sources, alignment, or removal of a gauge from service are more likely to exceed 10% of the limits as shown in **Table 4**. Applicants may be required to provide dosimetry (whole body and perhaps extremity monitors) to individuals performing such services or must perform a prospective evaluation demonstrating that unmonitored individuals performing such non-routine operations are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits as shown in **Table 4**.

Table 4. Occupational Dose Limits For Adults

Occupational Dose Limits for Adults (12VAC5-481-640)	
<u>Body Location</u>	<u>Dose (Annual)</u>
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	

When personnel monitoring is needed, most licensees use either film badges or Optically Stimulated Luminescence (OSLs) that are supplied by a NVLAP-approved processor. The exchange frequency for film badges is usually monthly due to technical concerns about film fading. Applicants should verify that the processor is NVLAP-approved. Consult the NVLAP-approved processor for its recommendations for exchange frequency and proper use.

Response from Applicant:

<p>Item 10.5 Occupational Dose (Check one box)</p> <p><input type="checkbox"/> We will maintain, for inspection by VDH, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in 12VAC5-481-640.</p> <p align="center">OR</p> <p><input type="checkbox"/> We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged at a frequency recommended by the processor.</p>
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Note:

- Alternative responses will be evaluated using the criteria listed above.
- Some licensees choose to provide personnel dosimetry to their workers for reasons other than compliance with VDH requirements (e.g., to respond 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.

Item 10.6: Public Dose

Rule: 12VAC5-481-10, 12VAC5-5481-630, 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 fixed gauges will be used, transported, and stored in such a way that members of the public will not receive more than 1 mSv [100 mrem] in one year, and the dose in any unrestricted area will not exceed 0.02 mSv [2 mrem] in any one hour, from licensed operations.
- Prevent unauthorized access, removal, or use of fixed gauges.

Discussion: Public dose is defined in 12VAC5-481-10 as “*the dose received by a member of the public from exposure to sources of radiation released by a licensee or registrant or to any other source of radiation under the control of licensee or registrant*”. Public dose excludes doses received from background radiation and from medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individuals assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) the individual is in when the dose is received.

In the case of fixed gauges, members of the public include persons who live, work, or may be near locations where fixed gauges are used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where gauges are used or stored. Since a fixed gauge presents a radiation field, the applicant must use methods to limit the public dose such that the radiation level in an unrestricted area (e.g., a nearby walkway or area near the gauge that requires frequent maintenance) does not exceed 1 mSv (100 mrem) in a year or 0.02 mSv (2 mrem) in any one hour.

Because fixed gauges are generally permanently mounted (e.g., chained and locked to a storage rack), they may not need to be in a locked area to prevent loss, theft, or unauthorized removal. Operating and emergency procedures regarding security and lock-out procedures specified in this document should be sufficient to limit the exposure to the public during use or storage and after accidents. IN 81-37, “*Unnecessary Radiation Exposures to the Public and Workers During Events Involving Thickness and Level Measuring Devices*”, dated December 15, 1981, provides information about two events that resulted or may have resulted in unnecessary radiation exposure to members of the public and to maintenance workers. IN 88-02, “*Lost or Stolen Gauges*”, dated February 2, 1988, provides information about several events where fixed gauges were lost or stolen.

Public dose is also affected by the location of the gauge. Use the concepts of time, distance, and shielding when developing a method to limit public dose. Decreasing the time spent near a gauge, increasing the distance from the gauge, and using shielding will reduce the radiation exposure. The most effective way to limit public dose is to prevent members of the public from entering areas where gauges are used or stored. This may be accomplished by administrative or engineering controls.

Administrative controls include training and warning signs. In cases where gauges are located in hostile environments (e.g., high temperatures, caustic chemicals, etc.), warning signs may be difficult to maintain so mandatory training programs may be necessary to caution employees.

Engineering controls reduce radiation levels in areas that are accessible to the public. Shielding the gauge with a protective barrier (e.g., using brick, concrete, lead, or other solid walls) or placing the gauge within an enclosure to prevent access to higher radiation levels are examples of engineering controls (**Table 5**).

When dose rates in an area are high enough that a member of the public could receive a dose in excess of 0.02 mSv (2 mrem) in any one hour or 1 mSv (100 mrem) in a year, licensees must take additional measures to prevent public access to these higher dose rates, such as building enclosures around the gauges.

Public dose can be estimated in areas near the gauge by using radiation levels determined during initial surveys and applying the 'inverse square' law to evaluate the effect of distance on radiation levels and occupancy factors to account for the actual presence of members of the public. See **Appendix K** for an example.

If, after making a public dose estimate, the conditions used to make the evaluation change (e.g., changes the location of gauges, changes the type or frequency of gauge use, adds gauges, changes the occupancy of adjacent areas), then the licensee must perform a new evaluation to ensure that the public dose limits are not exceeded and take corrective action, as needed.

Table 5. Methods to Limit Public Dose

Limiting Public Dose	
Administrative Controls	<ul style="list-style-type: none"> • Restrict access • Post Warning signs • Training
Engineering Controls	<ul style="list-style-type: none"> • Pre-planned storage/shielding • Security • New/additional shielding construction
Radiation Safety Concepts	<ul style="list-style-type: none"> • Time • Distance • Shielding • Surveys

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

Response from Applicant:

Item 10.6 Public Dose

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

References: IN 81-37, "Unnecessary Radiation Exposures to the Public and Workers During Events Involving Thickness and Level Measuring Devices", dated December 15, 1981, and IN 88-02, "Lost or Stolen Gauges", dated February 2, 1988 are located on the NRC's webpage at <http://www.nrc.gov>.

Item 10.7: Operating and Emergency Procedures

Rule: 12VAC5-481-450 A, 12VAC5-481-490, 12VAC5-481-630, 12VAC5-481-750, 12VAC5-481-840, 12VAC5-481-860, 12VAC5-481-880, 12VAC5-481-900, 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1150, 12VAC5-481-2260, 12VAC5-481-3091

Criteria: Each applicant must develop, implement, and maintain operating and emergency procedures containing the following elements:

- Instructions for operating the gauge
- Instructions for performing routine cleaning and maintenance (e.g., calibration and lubrication) according to the manufacturer's or distributors recommendations and instructions
- Instructions for testing each gauge for the proper operation of the on-off mechanism (shutter) and indicator, if any, at intervals not to exceed 6 months or as specified in the SSD certificate
- Instructions for lock-out procedures, if applicable, that are adequate to assure that no individual or portion of an individual's body can enter the radiation beam
- Instructions to prevent unauthorized access, removal, or use of fixed gauges
- Steps to take to keep radiation exposures ALARA
- Steps to maintain accountability (i.e., inventory)
- Instructions to ensure that non-routine operations such as installation, initial radiation survey, repair and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement and disposal of sealed sources, alignment, or removal of a gauge from service are performed by the manufacturer, distributor or person specifically authorized by VDH, the NRC or another Agreement State
- Steps to ensure that radiation warning signs are visible and legible.
- Develop, implement, and maintain emergency procedures for gauge malfunction or damage containing the following elements for each type of fixed gauge:
 - Stop use of the gauge.
 - Restrict access to the area.
 - Contact responsible individuals. (Telephone numbers for the RSO, AUs, the gauge manufacturer or distributor, fire department, and the agency should be posted or easily accessible.)
 - Do not attempt repair or authorize others to attempt repair of the gauge except as specifically authorized in a license issued by VDH, the NRC or another Agreement State.
 - Require timely reporting to the agency pursuant to 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110 or 12VAC5-481-1150.
 - Take additional steps, dependent on the specific situations.
- Provide copies of operating and emergency procedures to all gauge users.
- Post copies of operating and emergency procedures at each location of use or if posting procedures is not practicable, post a notice which briefly describes the procedures and states where they may be examined.

Discussion: The agency will permit an applicant greater flexibility if one or more of the following safety conditions are met. The applicant should clearly indicate which safety conditions are met for each fixed gauge:

- The air gap between the radiation source and detector of the device is less than 45 cm (18 inches)
- The air gap of the device would not allow insertion of a 30 cm (12 inches) diameter sphere into the radiation beam of the device without removal of a barrier
- The radiation dose rate in the radiation beam of the device at 45 cm (18 inches) from the radiation source with the device shutters, if any, in the open position does not exceed 1 mSv/hour (0.1 rem/hour)
- Entry into vessels (e.g., bins, tanks, hoppers, or pipes) with a gauge installed is not necessary under any foreseeable circumstances and is prohibited.

Operating and emergency procedures should be developed, maintained, and implemented to ensure that gauges are used only as they were designed to be used, control and accountability are maintained, and radiation doses received by occupational workers and members of the public are ALARA. This can be accomplished by adopting the procedures listed in **Item 10.7**, 'Operating and Emergency Procedures' Criteria.

Improper operation could lead to the damage or malfunction of a gauge and elevated exposure rates in the gauge's immediate vicinity. Emergency procedures should be developed to address a spectrum of incidents (e.g., fire, explosion, mechanical damage, flood, or earthquake) that could produce the potential for elevated exposure levels. A list of specific items that should be addressed in operating and emergency procedures is contained in **Appendix L**.

The agency considers security of licensed material extremely important and lack of security is a significant violation for which licensees may be fined. Although most fixed gauges are difficult to move, the licensee must prevent unauthorized access, removal, or use of the gauge. Licensees are responsible for ensuring that gauges are secure and accounted for at all times (e.g., during plant modifications, change in ownership, staffing changes, or after termination of activities at a particular location).

The agency must be notified when gauges are lost, stolen, or certain other conditions occur. The RSO must be proactive in evaluating whether agency notification is required. Refer to **Appendix P** and the regulations (12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1150) for a description of when and where notifications are required.

When the distance or air gap between the source and detector permits entry of all or a portion of a person's body into the primary radiation beam, licensees must develop lock out procedures. Lock-out procedures encompass locking the on-off or shutter mechanism into the off position or otherwise controlling the radiation beam or using any other means of preventing an individual or a portion of an individual's body from entering the radiation beam during maintenance, repairs, or work in, on, or around the process line (e.g., bin, tank, hopper, pipe, or conveyor belt) where the device is mounted. The on-off or shutter control mechanism should be tagged to indicate that the gauge is locked out. A warning sign should be posted at each entryway to an area where it is possible to be exposed to the primary beam. In addition to providing a warning, the sign should give safety instructions, e.g., "*contact the RSO before entering this vessel*". Lock-out procedures should specify who is responsible for performing them.

Response from Applicant:

Item 10.7 Operating and Emergency Procedures (Check one box)

- We will implement and maintain the operating and emergency procedures in Appendix L of VAREG 'Guidance for Fixed Gauge Devices' and provide copies of these procedures to all gauge users.

OR

- We will develop, implement and maintain operating and emergency procedures that will meet criteria in the section entitled 'Operating and Emergency Procedures' in VAREG 'Guidance for Fixed Gauge Devices'. (Procedures are attached)

Note Alternative procedures will be evaluated using the criteria listed above. If fixed gauges are used at Temporary Job Sites, additional procedures for the use of the fixed gauges addressing such issues as security (see **Item 10.12**) must be submitted.

Note: Telephone notifications shall be made to the agency at (804) 864-8150 during normal business hours (8 a.m. – 4:30 p.m.). For immediate notifications after normal business hours, the 24 hour emergency telephone number is (804) 674-2400 or (800) 468-8892. Identify the emergency as radiological.

References: The following Information Notices from NRC: IN 81-37, "*Unnecessary Radiation Exposures to the Public and Workers During Events Involving Thickness and Level Measuring Devices*", dated December 15, 1981; IN 86-31, "*Unauthorized Transfer and Loss of Control of Industrial Nuclear Gauges*", dated May 5, 1986; IN 88-02, "*Lost or Stolen Gauges*", dated February 2, 1988; IN 88-90 "*Unauthorized Removal of Industrial Nuclear Gauges*", dated November 22, 1988; and IN 94-15, "*Radiation Exposures during an Event Involving a Fixed Nuclear Gauge*", dated March 2, 1994 are located on the NRC's webpage at [Http://www.nrc.gov](http://www.nrc.gov).

Item 10.8: Leak Test

Rule: 12VAC5-481-180, 12VAC5-481-740, 12VAC5-481-1010, 12VAC5-481-1150

Criteria: The agency requires testing to determine whether there is any radioactive leakage from the source in the fixed gauge. 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, the NRC or another Agreement State. Records of the test results must be maintained.

Discussion: When issued, a license will require performance of leak tests at intervals approved by VDH, the NRC or another Agreement State as specified in the Registration Certificate. A leak test sample is collected according to the gauge manufacturers and the leak test kit supplier's instructions. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 microcurie) of radioactivity.

Manufacturers, distributors, consultants, and other organizations may be authorized by VDH, the NRC or another Agreement State to either perform the entire leak test sequence for other licensees or provide leak test kits to licensees. In the latter case, the licensee is expected to take

the leak test sample according to the fixed gauge manufacturer's and the kit supplier's instructions and return it to the kit supplier for evaluation and reporting results.

Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. Licensees may also be authorized to conduct the entire leak test sequence themselves. **Appendix M** contains information to support a request to perform leak testing and sample analysis.

Response from Applicant:

Item 10.8 Leak Test (Check one box)

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

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

Organization Name _____ License Number _____

Issuing Entity _____

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

OR

We will perform our own leak testing and sample analysis: We will follow the model procedures in Appendix M of VAREG 'Guidance for Fixed Gauge Devices'.

OR

We will submit alternative procedures. (Procedures are attached)

Note: Requests for authorization to perform leak testing and sample analysis will be reviewed and, if approved, VDH staff will authorize via a license condition.

References: Draft Regulatory Guide FC 412-4, "Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services", dated June 1985 is available on the NRC's webpage at <http://www.nrc.gov>

Item 10.9: Maintenance

Rule: 12VAC5-481-450 A, 12VAC5-481-490 B, 12VAC5-481-500, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-980

Criteria: Licensees must routinely clean and maintain gauges according to the manufacturer's or distributor's written recommendations and instructions. Individuals performing routine maintenance must have adequate training and experience. Radiation safety procedures for routine cleaning and maintenance (e.g., removal of exterior residues from the gauge housing, external

lubrication of shutter mechanism, calibration, and electronic repairs) must consider ALARA and ensure that the gauge functions as designed and source integrity is not compromised.

Non-routine maintenance or repair (beyond routine cleaning, lubrication, calibration, and electronic repairs) means any maintenance or repair that involves or potentially affects components, including electronics, related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control or shielding) and any other activities during which personnel could receive radiation doses exceeding the agency limits.

Non-routine repair or maintenance must be performed by the fixed gauge manufacturer or distributor or a person specifically authorized by VDH, the NRC or another Agreement State. Licensees need to perform routine maintenance to ensure proper operation of the fixed gauge. For non-routine maintenance, most licensees rely on the gauge manufacturer, distributor or other service companies. Information to support requests for specific authorization to perform non-routine maintenance or repair is addressed in **Appendix N**.

Discussion: VDH permits fixed gauge licensees to perform routine maintenance of the gauges provided that they follow the gauge manufacturer's or distributor's written recommendations and instructions. Generally, before any maintenance or repair work is done, licensees need to determine (and assure themselves of the adequacy of) the following:

- The tasks to be performed
- The protocol or procedures to be followed
- The radiation safety procedures including possible need for compensatory measures (e.g., steps taken to compensate for lack of or reduced shielding)
- ALARA considerations
- Training and experience of personnel performing the work
- The qualification of parts, components, other materials to be used in the gauge
- The tests (to be performed before the gauge is returned to routine use) to ensure that it functions as designed.

Although manufacturers or distributors may use different terms, 'routine maintenance' includes, but is not limited to, cleaning, lubrication, calibration, and electronic repairs. Routine maintenance does **not** include any activities that involve:

- Components, including electronics, related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control or shielding);
- Installation, relocation, or alignment of the gauge;
- Initial radiation surveys;
- Replacement and disposal of sealed sources;
- Removal of a gauge from service;
- A potential for any portion of the body to come into contact with the primary radiation beam; or
- Any other activity during which personnel could receive radiation doses exceeding the VDH limits.

Mounting a gauge is unpacking or uncrating the gauge, and fastening, hanging, or affixing the gauge into position before using. Mounting does not include electrical connection, activation, or

operation of the gauge. Installing a gauge includes mounting, electrical connection, activation, and first use of the device. Specific VDH, NRC or another Agreement State authorization is required to install a gauge. However, a licensee may initially mount a gauge, without specific VDH, NRC or another Agreement State authorization, if the gauge's SDDR Certificate explicitly permits it and under the following guidelines:

- The gauge must be mounted according to written instructions provided by the manufacturer or distributor
- The gauge must be mounted in a location compatible with the "*Conditions of Normal Use*" and "*Limitations and/or Other Considerations of Use*" in the certificate of registration issued by the NRC or another Agreement State
- The on-off mechanism (shutter) must be locked in the off position, if applicable, or the source must be otherwise fully shielded
- The gauge must be received in good condition (package was not damaged)
- The gauge must not require any modification to fit in the proposed location.

The source must remain fully shielded and the gauge may not be used until it is installed and made operational by a person specifically licensed by VDH, the NRC or another Agreement State to perform such operations.

A condition in the VDH license will state that operations such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement, and disposal of sealed sources, alignment, or removal of a gauge from service shall be performed only by the manufacturer, distributor or other persons specifically licensed by VDH, the NRC or another Agreement State to perform such services. Most licensees do not perform non-routine operations. Rather, these licensees rely upon persons specifically licensed by VDH, the NRC or another Agreement State who have the specialized equipment and technical expertise needed to perform these activities. Applicants seeking authorization to perform non-routine operations must submit specific procedures for review. See **Appendix N** for more information.

Response from Applicant:

Item 10.9 Maintenance (Check one box for Routine Cleaning and Lubrication and one for Non-Routine Maintenance)

ROUTINE CLEANING AND LUBRICATION:

We will implement and maintain procedures for routine maintenance of our gauges according to each manufacturer's recommendations and instructions.

OR

Alternative procedures are attached.

NON-ROUTINE MAINTENANCE:

We will utilize the manufacturer or another person specifically licensed to perform non-routine maintenance or repair operations that require the removal of the source from the device. Radiation surveys required by **12VAC5-481-750** will be performed by a person specifically authorized by VDH, the NRC or another Agreement State.

OR

We have provided the information listed in Appendix N of VAREG 'Guidance for Fixed Gauge Devices' to support a request to perform this work 'in house'. (Procedure are attached)

Note:

- Alternative procedures for performing routine maintenance will be evaluated using the criteria listed above.
- Information requested in **Appendix N** will be reviewed on a case-by-case basis; if approved, the license will contain a condition authorizing the licensee to perform non-routine operations.

Item 10.10: Fixed Gauge Disposal and Transfer

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-910, 12VAC5-481-980, 12VAC5-481-2980, 12VAC5-481-3100

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

Discussion: When disposing of fixed gauges, licensees must transfer them to an authorized recipient. Authorized recipients are the original manufacturer or distributor of the device, a commercial firm licensed by VDH, the NRC or another Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the radioactive material (i.e., its license specifically authorizes the same radionuclide, form, and use).

Before transferring radioactive material, a licensee must verify that the recipient is properly authorized to receive it using one of the methods described in **12VAC5-481-570 D**. In addition, all packages containing radioactive sources must be prepared and shipped in accordance with the VDH and DOT regulations. Records of the transfer must be maintained as required by **12VAC5-481-100** and **12VAC5-481-571**.

Response from Applicant:

<p>Item 10.10 Fixed Gauge Disposal and Transfer (check box)</p> <p><input type="checkbox"/> We will return the gauge to the manufacturer for disposal or transfer the device to a specific licensee authorized to receive radioactive material.</p>
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Because of the difficulties and costs associated with disposal of sealed sources, applicants should preplan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement. Significant problems can arise from improper gauge transfer or failure to dispose of gauges in a proper and timely manner. See Information Notice 86-31, "*Unauthorized Transfer and Loss of Control of Industrial Nuclear Gauges*", dated May 5, 1986, and IN 88-02, "*Lost or Stolen Gauges*", dated February 2, 1988.

References: NRC IN 86-31, "*Unauthorized Transfer and Loss of Control of Industrial Nuclear Gauges*", dated May 5, 1986 and NRC IN 88-02, "*Lost or Stolen Gauges*", dated February 2, 1988 are available at the NRC's webpage <http://www.nrc.gov>.

Item 10.11: Transportation

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

Criteria: Applicants must either:

- Arrange for transportation of a gauge by the manufacturer, distributor or other person specifically licensed to transport gauges by VDH, the NRC or another Agreement State.
OR
- Develop, implement, and maintain safety procedures for off-site transport of radioactive material to ensure compliance with DOT regulations.

Discussion: Some fixed gauge licensees have the manufacturer, distributor or other person specifically licensed to transport gauges by VDH, the NRC or another Agreement State arrange for preparing and shipping licensed material. If licensees decide to transport their own gauges, they are responsible for compliance with DOT regulations which require, in part, specific labeling and surveying of the package before shipping. To appropriately survey the package the surveyor must use instruments that can measure radiation exposure rates around the package and detect contamination on the package. **Appendix O** lists major DOT regulations and provides an example of a shipping paper. During an inspection, the agency uses the provisions of 12VAC5-481-2980 to examine and enforce transportation requirements applicable to gauge licensees.

Response from Applicant:

Item 10.11 Transportation

No response is needed from applicants during the licensing process; this issue will be reviewed during inspection.

References: "*A Review of Department of Transportation Regulations for Transportation of Radioactive Materials (1998 revision)*" can be obtained by calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4425.

Item 10.12: Fixed Gauges Used at Temporary Job Sites

Rule: 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-590, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-750, 12VAC5-481-840, 12VAC5-481-860, 12VAC5-481-880, 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-2980, 12VAC5-481-3100

Criteria: Each applicant requesting authorization to perform work with fixed gauges at temporary job sites should develop, implement, maintain, and distribute operating and emergency procedures containing the following elements:

- Instructions for transporting radioactive material to ensure compliance with DOT regulations
- Instructions for using gauges at temporary job sites and performing routine maintenance according to the manufacturer's or distributor's recommendations and instructions
- Instructions for maintaining security during storage and transportation
- Instructions to keep gauges under control and immediate surveillance or secured to prevent unauthorized use or access.
- Steps to take to keep radiation exposures ALARA
- Steps to maintain accountability during use
- Steps to control access to a potentially damaged gauge
- Steps to take, and who to contact, when a gauge has been lost or damaged (e.g., local officials, RSO, etc.)
- If gauges are to be installed at temporary job sites, the operating and emergency procedures should contain instructions on using personal dosimetry and survey instruments and conducting surveys
- Provide copies of operating and emergency procedures to all gauge users and at each job site.

Discussion: A temporary job site is a location where work with licensed materials is conducted for a limited period of time. Temporary job sites are not specifically listed on a license. A gauge user may be dispatched to work at several temporary job sites in one day. A location is not considered a temporary job site if it is used to store and dispatch radioactive material. The agency considers such a location to be a field office. Licensees must apply for and receive a license amendment specifically listing each field office location. Licensee personnel implement emergency procedures when a traffic accident results in a damaged gauge and potentially elevated exposure levels.

There are two categories of fixed gauges used at temporary job sites: Gauges that are permanently mounted to vehicles or trailers, and gauges that are transported to plants or refineries and temporarily installed on process equipment to conduct short-term QA/QC studies.

Applicants must develop, implement, and maintain safety procedures for off-site transport of radioactive material to ensure compliance with DOT regulations. During an inspection, the agency will use the provisions of **12VAC5-481-2980** to examine and enforce transportation requirements applicable to fixed gauge licensees. **Appendix O** lists major DOT regulations and provides examples of shipping documents, placards, and labels.

When working at a temporary job site, licensees generally have to follow the rules and procedures of the organization that owns or controls the site. Thus, licensees may not be able to restrict access to areas in the same manner that they could at their own facilities. Furthermore, non-licensee personnel may not be familiar with fixed gauges or radioactive material. Therefore, to avoid lost or stolen gauges and to prevent unnecessary radiation exposures to members of the public, licensees must keep gauges under constant surveillance, or secured against unauthorized use or removal.

While installing gauges, personnel could receive radiation doses exceeding VDH limits if proper radiation safety principles are not followed. Licensee personnel performing installations should be assigned and wear personal dosimetry and use a survey meter to monitor radiological conditions.

After installing a gauge at a temporary job site, a radiation survey should be conducted to ensure that dose rates in unrestricted areas will not exceed 0.02 mSv (2 mrem) in any one hour or 1 mSv (100 mrem) in a year. If surveys indicate that a member of the public (e.g., client personnel) could receive a dose exceeding these limits, licensees would need to adopt additional security measures to prevent public access such as maintaining constant surveillance or erecting physical barriers.

Response from Applicant:

Item 10.12 Fixed Gauges Used at Temporary Job Sites (Check one box)	
<input type="checkbox"/>	We will submit procedures for the use of fixed gauges at temporary job sites (Procedures are attached)
OR	
<input type="checkbox"/>	No temporary job sites used.

Item 11: License Fees

On VDH Form, 'Application for Radioactive Material License Authorizing the Use of Sealed Sources in Fixed Gauge Devices' (**Appendix A**) enter the fee category and the amount. Refer to **12VAC5-490** for fee category and application fees. Enclose fee with the application.

Response from Applicant:

SPECIFIC LICENSE FEE	
Item 11 License Fees (Refer to 12VAC5-490.)	
Category:	License fee enclosed: <input type="checkbox"/> Yes <input type="checkbox"/> No Amount Enclosed _____

Item 12: Certification

Criteria:

- Individuals acting in a private capacity are required to sign and date VDH Form, 'Application for Radioactive Material License Authorizing the Use of Sealed Sources in Fixed Gauge Devices' (**Appendix A**).
- Senior representatives of the corporation or legal entity filing the application should sign and date VDH Form, 'Application for Radioactive Material License Authorizing the Use of Sealed Sources in Fixed Gauge Devices' (**Appendix A**).

Representatives signing an application must be authorized to make binding commitments and sign official documents on behalf of the applicant. As discussed previously in

'Management Responsibility', signing the application acknowledges management's commitment and responsibilities for the radiation protection program. **The agency will return all unsigned applications for proper signature.**

Response from Applicant:

Item 12	
I hereby certify that this application was prepared in conformance with 12VAC5-481 'Virginia Radiation Protection Regulations' and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.	
SIGNATURE - Applicant Or Authorized Individual	Date signed
Print Name and Title of above signatory	

Note:

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

Appendix A

VDH Form

‘Application for Radioactive Material License Authorizing the Use of Sealed Sources in Fixed Gauge Devices’

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



APPLICATION FOR RADIOACTIVE MATERIAL LICENSE AUTHORIZING THE USE OF SEALED SOURCES IN FIXED GAUGE DEVICES

Virginia Department of Health is requesting disclosure of information. Failure to provide any information may result in denial or delay of a radioactive material license.

Instructions – Complete all items if this is an initial application or an application for renewal of a license. Refer to VAREG “Guidance for Fixed Gauge Devices.” Use supplementary sheets where necessary. Retain one copy and submit original of the entire application to the Commonwealth of Virginia, Department of Health (VDH), 109 Governor Street, Post Office Box 2448, Richmond, VA 23218.

APPLICATION TYPE

Item 1. Type Of Application (Check one box)

New License Renewal License Number: _____

CONTACT INFORMATION

<p>Item 2. Name And Mailing Address Of Applicant:</p> <p>Applicant’s Telephone Number (Include Area Code):</p>	<p>Item 3. Person To Contact Regarding Application:</p> <p>Contact’s Telephone Number (Include Area Code):</p>
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LOCATION OF RADIOACTIVE MATERIAL

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

Address	Telephone Number (Include Area Code)
Address	Telephone Number (Include Area Code)
Address	Telephone Number (Include Area Code)

RADIATION SAFETY OFFICER

Item 5. Radiation Safety Officer (RSO) (Check one box and attach evidence of training and experience)

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

Before obtaining radioactive material, the proposed RSO will have successfully completed one of the training courses described in Criteria in the section titled “Radiation Safety Officer” in VAREG ‘Guidance For Fixed Gauge Devices’. Before being named as the RSO, future RSOs will have successfully completed one of the training courses described in Criteria in the section titled ‘Radiation Safety Officer’ in VAREG “Guidance For Fixed Gauge Devices”.

Or

Alternative information demonstrating that the proposed RSO is qualified by training and experience is attached. Before being named as the RSO, future RSOs will have successfully completed one of the training courses described in Criteria in the section titled ‘Radiation Safety Officer’ in VAREG “Guidance For Fixed Gauge Devices”.

Item 10.3 Survey Instruments And Instrument Calibration (Check all that apply)

- We will have access to a survey meter that meets the Criteria in the section titled "Survey Instruments" in VAREG "Guidance for Fixed Gauge Devices." (Description attached)
Or
- We will possess a survey meter that meets the Criteria in the section titled "Survey Instruments" in VAREG "Guidance for Fixed Gauge Devices."

AND ONE OF THE FOLLOWING

- Each survey meter will be calibrated by an organization licensed by VDH, the NRC or an Agreement State to perform survey meter calibrations.
Or
- We will implement the model survey meter calibration program published in Appendix I in VAREG "Guidance for Fixed Gauge Devices."
Or
- We will submit alternative calibration procedures for VDH review. (Procedures are attached)

Item 10.4 Material Receipt And Accountability (Check one box)

- Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license.
Or
- We will submit a description of the frequency and procedures for ensuring that no gauge has been lost, stolen or misplaced. (Procedures are attached)

Item 10.5 Occupational Dose (Check one box)

- We will maintain, for inspection by VDH, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in 12VAC5-481-640.
Or
- We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged at a frequency recommended by the processor.

Item 10.6 Public Dose

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

Item 10.7 Operating And Emergency Procedures (Check one box)

- We will implement and maintain the operating and emergency procedures in Appendix L of VAREG "Guidance for Fixed Gauge Devices" and provide copies of these procedures to all gauge users.
Or
- We will develop, implement and maintain operating and emergency procedures that will meet criteria in the section titled "Operating and Emergency Procedures" in VAREG "Guidance for Fixed Gauge Devices." (Procedures are attached)

Item 10.8 Leak Test (Check one box)

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

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

Organization Name _____ License Number _____

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

- We will perform our own leak testing and sample analysis. We will follow the model procedures in Appendix M of VAREG "Guidance for Fixed Gauge Devices."
Or
- We will submit alternative procedures. (Procedures are attached)

Item 10.9 Maintenance (Check one box for routine cleaning and lubrication and one for non-routine maintenance)

ROUTINE CLEANING AND LUBRICATION:

We will implement and maintain procedures for routine maintenance of our gauges according to each manufacturer's recommendations and instructions.

Or

Alternative procedures are attached.

NON-ROUTINE MAINTENANCE:

We will utilize the manufacturer or another person specifically licensed to perform non-routine maintenance or repair operations that require the removal of the source from the device. Radiation surveys required by 12VAC5-481-750 will be performed by a person specifically authorized by VDH, the NRC or an Agreement State.

Or

We have provided the information listed in Appendix N of VAREG "Guidance for Fixed Gauge Devices" to support a request to perform this work "in house." (Procedures are attached)

Item 10.10 Fixed Gauge Disposal And Transfer (Check one box)

We will return the gauge to the manufacturer for disposal or transfer the device to a specific licensee authorized to receive radioactive material.

Item 10.11 Transportation

No response is needed from applicants during the licensing process; this issue will be reviewed during inspection.

Item 10.12 Fixed Gauges used at Temporary Job Sites (Check one box)

We will submit procedures for the use of fixed gauges at temporary job sites. (Procedures are attached)

Or

No temporary job sites used.

SPECIFIC LICENSE FEE

Item 11. License Fees (12VAC5-490)

Category:

License fee enclosed

Yes No Amount Enclosed _____

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

Item 12

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

SIGNATURE - Applicant or Authorized Individual

Date signed

Print Name and Title of above signatory

Appendix B

VDH Form

‘Certificate of Disposition of Materials’

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



CERTIFICATE OF DISPOSITION OF MATERIALS

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

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

CONTACT INFORMATION

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

TERMINATION AND DISPOSITION INFORMATION

The following information is provided in accordance with 12VAC5-481-510. (Check all that apply)

- Item 4** All use of radioactive material authorized under the above referenced license has been terminated.
- Item 5** Radioactive contamination has been removed to the levels outlined in 12VAC5-481-1161 B.
- Item 6** All radioactive material previously procured and/or possessed under the authorization granted by the above referenced license has been disposed of as follows. (Check all that apply)
 - Transferred to: Name Address

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

Issued by (Licensing Agency):

- Decayed, surveyed and disposed of as non-radioactive waste.
- No radioactive material has ever been procured and/or possessed by the licensee under the authorization granted by the above referenced license.
- Other (Attach additional pages)

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

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

Name:

Address:

Contact Person Telephone Number: () - X

Additional remarks (Attach additional pages if necessary.)

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

Item 10.

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

SIGNATURE - Applicant or Authorized Individual

Date signed

Print Name and Title of Above Signatroy

Appendix C

Information Needed for Transfer of Control Application

Information Needed for Transfer of Control Application

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

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

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

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

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

References: The information above is derived from NRC Information Notice 89-25, Revision 1, "*Unauthorized Transfer of Ownership or Control of Licensed Activities*", which is available at the NRC's webpage at <http://www.nrc.gov>.

Appendix D

Reserved

Appendix E

Model Delegation of Authority (RSO)

Memo to: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with the rule. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Virginia Department of Health, Radioactive Materials Program at anytime. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

Signature of Management Representative

I accept the above responsibilities,

Signature of Radiation Safety Officer

cc: Affected department heads.

Appendix F

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 both VDH regulations and the conditions of the license. The RSO's duties and responsibilities include ensuring the following:

- Activities involving licensed material that the RSO considers unsafe are stopped
- Radiation exposures are ALARA
- Development, maintenance, distribution, and implementation of up-to-date operating and emergency procedures
- Individuals that use fixed gauges are properly trained
- Possession, installation, relocation, use, storage, routine maintenance and non-routine operations of fixed gauges are consistent with the limitations in the license, the SDDR Certificate(s), manufacturer's or distributor's recommendations and instructions
- Safety consequences of non-routine operations are analyzed before conducting any such activities that have not been previously analyzed
- Non-routine operations are performed by the manufacturer, distributor or person specifically authorized by VDH, the NRC or another Agreement State
- Prospective evaluations are performed demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or personnel monitoring devices are provided
- Personnel monitoring devices, if required, are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained
- Documentation is maintained to demonstrate, 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 in **12VAC5-481-720**.
- Fixed gauges are properly secured
- Notification of proper authorities of incidents such as damage to or malfunction of fixed gauges, fire, loss, or theft
- Investigation of unusual occurrences involving the fixed gauge (e.g., malfunctions or damage), identification of cause(s), implement of appropriate and timely corrective action(s)
- Radiation safety program audits are performed at intervals not to exceed 12 months and should include development, implementation, and documentation of timely corrective actions
- Radioactive material is transported according to all applicable DOT requirements
- Radioactive material is disposed of properly

- Appropriate records are maintained
- An up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner
- Posting of documents required by **12VAC5-481-2260** (license documents, operating procedures, VDH Form, 'Notice to Employees').

Appendix G

Criteria for Acceptable Training for Authorized Users and Radiation Safety Officers

Criteria for Acceptable Training for Authorized Users and Radiation Safety Officers

Course Content

Classroom training may be in the form of lecture, videotape, or self-study emphasizing practical subjects important to safe use of the gauge.

Radiation Safety:

- Radiation vs. contamination
- Internal vs. external exposure
- Biological effects of radiation
- Types and relative hazards of radioactive material possessed
- ALARA concept
- Use of time, distance, and shielding to minimize exposure
- Location of sealed source within the gauge

Regulatory Requirements:

- Applicable regulations
- License conditions, amendments, renewals
- Locations of use and storage of radioactive materials
- Material control and accountability
- Annual audit of radiation safety program
- Transfer and disposal
- Recordkeeping
- Prior events involving fixed gauges
- Handling incidents
- Recognizing and ensuring that radiation warning signs are visible and legible
- Licensing and inspection by VDH
- Need for complete and accurate information
- Employee protection
- Deliberate misconduct

Practical Explanation of the Theory and Operation for Each Gauge Possessed by the Licensee:

- Operating and emergency procedures
- Routine vs. non-Routine maintenance
- Lock-out procedures

On-the-job training must be done under the supervision of an Authorized User or Radiation Safety Officer:

- Supervised Hands-on Experience Performing:
 - Operating procedures
 - Test runs of emergency procedures
 - Routine maintenance
 - Lock-out procedures

Training Assessment

Management will ensure that proposed Authorized Users are qualified to work independently with each type of gauge with which they may work. Management will ensure that proposed Radiation Safety Officer's are qualified to work independently with and are knowledgeable of the radiation safety aspects of all types of gauges to be possessed by the applicant. This may be demonstrated by written or oral examination or by observation.

Course Instructor Qualifications

Instructor should have:

- Bachelor's degree in a physical or life science or engineering
 - Successful completion of a fixed gauge manufacturer's or distributor's course for users (or equivalent)
 - Successful completion of an 8 hour radiation safety course; and
 - 8 hours hands-on experience with fixed gauges
- OR**
- Successful completion of a fixed gauge manufacturer's or distributor's course for users (or equivalent)
 - Successful completion of 40 hour radiation safety course; and
 - 30 hours of hands-on experience with fixed gauges.
- OR**
- The applicant may submit a description of alternative training and experience for the course instructor.

Note: Additional training is required for those applicants intending to perform non-routine operations such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement, and disposal of sealed sources, alignment, or removal of a gauge from service. See **Appendix N**.

Appendix H

Suggested Fixed Gauge Audit Checklist

Suggested Fixed Gauge Audit Checklist

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

Licensee's name:	License No.:
Date of this Audit:	Date of Last Audit:
Auditor Signature:	Date:
Management Signature:	Date:

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?
- B. If ownership changed or bankruptcy filed, was VDH's prior consent obtained or was the agency notified?
- C. Radiation Safety Officer:
 1. If the RSO was changed, was license amended?
 2. Does new RSO meet VDH requirements?
 3. Is RSO fulfilling his or her duties?
 4. To whom does the RSO report?
- D. If the designated contact person for the agency changed, was the agency notified?
- E. Sealed Sources and Devices
 1. Does the license authorize all of VDH's regulated radionuclides contained in gauges?
 2. Are the gauges as described in the Sealed Source and Device Registration (SSDR) Certificate?
 3. Have copies of (or access to) SSDR Certificates?
 4. Have manufacturers' or distributor's manuals for operation and maintenance?
 5. Are the actual uses of gauges consistent with the authorized uses listed on the license?
 6. Are the locations of the gauges compatible with the "*Conditions of Normal Use*" and "*Limitations and/or Other Considerations of Use*" on the SSDR Certificates?

Training and Instructions to Workers

- A. Were all workers who are likely to exceed or exceed 1 mSv (100 mrem) in a year instructed per **12VAC5-481-2270**? Annual training provided, as needed **12VAC5-481-2270**? Records maintained?
- B. Did each Authorized User (AU) receive training and instruction given at the time of gauge installation or equivalent training and instruction before using gauges?
- C. Are training records maintaining for each AU?
- D. Did individuals who perform non-routine operations receive training before performing these operations?

- E. Did interviews with AUs reveal that they know the emergency procedures?
- F. Did this audit include observations of AUs using the gauge?
- G. Did this audit include observations of workers performing routine cleaning and lubrication on the gauge?
- H. HAZMAT training provided, if required? [49 CFR 172.700; 172.701; 172.702; 172.703; 172.704]

Radiation Survey Instruments

- A. If the licensee is required to possess a survey meter, does it meet the agency's criteria? (12VAC5-481-750)
- B. Are calibration records maintained? (12VAC5-481-1000)

Gauge Inventory

- A. Is a record kept showing the receipt of each gauge? (12VAC5-481-100, 12VAC5-481-571)
- B. Are all gauges physically inventoried every six months?
- C. Are records of inventory results with appropriate information maintained?

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 or equal to 10% of the limit? (12VAC5-481-640, 12VAC5-481-760)
- C. Did unmonitored individuals' activities change during the year which could put the 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 limit)? And is dosimetry provided to those individuals?
 - 1. Is the dosimetry supplier NVLAP approved? (12VAC5-481-750)
 - 2. Are the dosimeters exchanged at the appropriate frequency (for example monthly for film badges)?
 - 3. Are dosimetry reports reviewed by the RSO when they are received?
 - 4. Are the records VDH forms or equivalent? (12VAC5-481-1000; 12VAC5-481-1040, 12VAC5-481-1080)
 - a. VDH Form, 'Cumulative Occupational Exposure History' completed?
 - b. VDH Form, 'Occupational Exposure Record for a Monitoring Period' completed?
 - 5. Declared pregnant worker/embryo/fetus
 - a. If a worker declared her pregnancy, did licensee comply with 12VAC5-481-710?
 - b. Were records kept of embryo/fetus dose 12VAC5-481-1040?
 - 6. Are annual exposure reports given to employees who receive greater than 100 mrem per year? (12VAC5-481-2280)
- F. Are records of exposures, surveys, monitoring, and evaluations maintained? (12VAC5-481, Part IV, Article 12)

Public Dose

- A. Is public access to gauges controlled in a manner to keep doses below 1mSv (100 mrem) in a year?
(12VAC5-481-720, 12VAC5-481-730)
- B. Has a survey or evaluation been performed per 12VAC5-481-730? Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?
- C. Do unrestricted area radiation levels exceed 0.02mSv (2mrem) in any one hour?
(12VAC5-481-720)
- D. Is gauge access controlled in a manner that would prevent unauthorized use or removal?
(12VAC5-481-840)
- E. Records maintained? (12VAC5-481-1050)

Operating and Emergency Procedures

- A. Have operating and emergency procedures been developed?
- B. Do they contain the required elements?
- C. Does each individual working with the gauges have a current copy of the operating and emergency procedures (including lock-out procedures and emergency telephone numbers)?
- D. Is a lock-out warning sign posted at each entryway to an area where it is possible to be exposed to the beam?
- E. Did any emergencies occur?
 - 1. If so, were they handled properly?
 - 2. Were appropriate corrective actions taken?
 - 3. Was agency notification or reporting required? (12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1150)

Leak Tests

- A. Was each sealed source leak tested every 6 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 and if yes, was the agency notified?

Maintenance of Gauges

- A. Are manufacturer's or distributor's procedures followed for routine cleaning and lubrication of gauge?
- B. Was each on-off mechanism tested for proper operation every 6 months or at other prescribed intervals?
- C. Are repair and maintenance of components related to the radiological safety of the gauge performed by the manufacturer, distributor or person specifically authorized by VDH, the NRC or an Agreement State and according to license requirements (e.g., extent of work, procedures, dosimetry, survey instrument, compliance with 12VAC5-481-640 limits)?
- D. Are labels, signs, and postings identifying gauges containing radioactive material, radiation areas, and lock-out procedures/warnings clean and legible?

Transportation

(Note: This section will not apply if you have not transported gauges during the period covered by this audit.)

- A. DOT-7A or other authorized package used? (49 CFR 173.415; 173.416(b))
- B. Package performance test records on file if licensee performs shipment?
- C. Special form sources documentation? (49 CFR 173.476(a))
- D. Package has two labels (ex. Yellow-II) with TI, Nuclide, Activity, and Hazard Class? (49 CFR 172.403; 173.441)
- E. Package properly marked? (49 CFR 172.301; 172.304; 172.310; 172.324)
- F. Package closed and sealed during transport? (49 CFR 173.475(f))
- G. Shipping papers prepared and used? (49 CFR 172.200(a))
- H. Shipping papers contain proper entries? {Shipping name, Hazard Class, Identification Number (UN Number), Total Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity (SI units required), category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, Cargo Aircraft Only (if applicable)} (49 CFR 172.200; 172.201; 172.202; 172.203; 172.204; 172.604)
- I. Shipping papers within drivers reach and readily accessible during transport? (49 CFR 177.817(e))
- J. Package secured against movement? (49 CFR 177.834)
- K. Placards on vehicle, if needed? (49 CFR 172.504)
- L. Proper overpacks, if needed? (49 CFR 173.25)
- M. Any incidents reported to DOT or the agency? (49 CFR 171.15; 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?

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, 12VAC5-481-1150)
- C. Did any overexposures or high radiation levels occur? Reported? (12VAC5-481-1100, 12VAC5-481-1110)
- D. If any events (as described in items a through c above) did occur, what was the root cause? Were corrective actions appropriate?
- E. Is the management/RSO/shift foreman licensee aware of the telephone number for the agency? (During business hours: (804) 864-8150 or 24 hour emergency number (804) 674-2400 or (800) 468-8892. Identify the emergency as radiological).

Posting and Labeling

- A. VDH Form, 'Notice to Employees' posted? (12VAC5-481-2260 C)
- B. The VDH rule, license documents posted or a notice posted? (12VAC5-481-2260 A)
- C. Other postings and labelings? (12VAC5-481-860, 12VAC5-481-880, 12VAC5-481-2260)

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?

Bulletins and Information Notices

- A. VDH bulletins, Information Notices, NRC Information Notices, NMSS Newsletters, received?
- B. Appropriate training and action taken in response?

Special License Conditions or Issues

- A. Did auditor review special license conditions or other issues (e.g., non-routine operations)?

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. Are corrective actions planned or taken at ALL licensed locations (not just location audited)? 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 or her radiation safety duties?
- C. Licensee has sufficient staff to support the radiation protection program?

Appendix I

Model Survey Instrument Calibration Program

Model Survey Instrument Calibration Program

Training

Before independently calibrating survey instruments, an individual should complete both classroom and on-the-job training as follows:

- Classroom training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:
 - Principles and practices of radiation protection
 - Radioactivity measurements, monitoring techniques, and the use of instruments
 - Mathematics and calculations basic to using and measuring radioactivity
 - Biological effects of radiation.
- On-the-job training will be considered complete if the individual has:
 - Observed authorized personnel performing survey instrument calibration; and
 - Conducted survey meter calibrations under the supervision, and in the physical presence of an individual already authorized to perform calibrations.

Facilities and Equipment

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

Model Procedure for Calibrating Survey Instruments

- A radioactive sealed source(s) will be used for calibrating survey instruments, and this source will:
 - Approximate a point source
 - Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified to be within $\pm 5\%$ accuracy by National Institutes of Standards and Technology (NIST)
 - Contain a radionuclide which emits radiation of identical or similar type and energy as the sealed sources that the instrument will measure
 - Be strong enough to emit a radiation field that is representative of the field being emitted by the gauge. For calibration of instruments intended to measure gamma radiation, the exposure rate should be at least 30 mR/hour (7.7 microcoulomb/kilogram per hour) at 100 cm [e.g., 3.1 gigabecquerels (85 millicuries) of Cs-137 or 780 megabecquerels (21 millicuries) of Co-60].
- Inverse square and radioactive decay laws must be used to correct changes in exposure rate due to changes in distance or source decay.
- A record must be made of each survey meter calibration.
- A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than $\pm 20\%$.
- There are three kinds of scales frequently used on radiation survey meters. They are calibrated either as described in ANSI N323A-1996, "American National Standard

Radiation Protection Instrumentation Test and Calibration - Portable Survey Instruments", or as follows:

- Meters on which the user selects a linear scale must be calibrated at not fewer than two points on each scale. The points will be at approximately 1/3 and 2/3 of the decade.
- Meters that have a multidecade logarithmic scale must be calibrated at one point (at the least) on each decade and not fewer than two points on one of the decades. Those points will be approximately 1/3 and 2/3 of the decade.
- Meters that have an automatically ranging digital display device for indicating exposure rates must be calibrated at one point (at the least) on each decade and at no fewer than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.
- Readings above 200 mR/hour (50 microcoulomb/kilogram per hour) need not be calibrated. However, higher scales should be checked for operation and approximately correct response.
- Survey meter calibration reports will indicate the procedure used and the results of the calibration. The reports will include:
 - The owner or user of the instrument
 - A description of the instrument that includes 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 on a specified date, and the calibration procedure
 - For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument
 - The exposure reading indicated with the instrument in the 'battery check' mode (if available on the instrument)
 - For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)
 - For instruments with internal detectors, the angle between 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 from a check source, if used
 - The signature of the individual who performed the calibration and the date on which the calibration was performed.
- The following information will be attached to the instrument as a calibration sticker or tag:
 - The source that was used to calibrate the instrument
 - The proper deflection in the battery check mode (unless this is clearly indicated on the instrument)
 - For each scale or decade not calibrated, an indication that the scale or decade was checked only for function but not calibrated
 - The date of calibration and the next calibration due date
 - The apparent exposure rate from the check source, if used.

References: Detailed information about survey instrument calibration may be obtained by referring to ANSI N323A-1996, "*American National Standard Radiation Protection Instrumentation Test and*

Calibration -Portable Survey Instruments". Copies may be ordered electronically at <http://www.ansi.org> or by writing to ANSI, 1430 Broadway, New York, NY 10018. NRC RG FC 413-4, "*Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments*", dated June 1985.

Appendix J

Guidance for Demonstrating that Unmonitored Individuals Are Not Likely to Exceed 10 Percent of the Allowable Limits

Guidance for Demonstrating That Unmonitored Individuals Are Not Likely to Exceed 10 Percent of the Allowable Limits

Dosimetry is required for individuals likely to receive, in 1 year from sources external to the body, a dose in excess of 10% of the applicable regulatory limits in **12VAC5-481-640**. To demonstrate that dosimetry is not required, a licensee needs to perform a prospective evaluation to demonstrate that its workers are not likely to exceed 10% of the applicable annual limits.

The most common way that individuals might exceed 10% of the applicable limits is by performing frequent routine maintenance on the gauge. However, for most gauges even these activities result in the individual receiving minimal doses. Before allowing workers to perform these tasks, a licensee will need to evaluate the doses which its workers might receive to assess whether dosimetry is required; this is a prospective evaluation.

Example

One gauge manufacturer has estimated the doses to the extremities and whole body of a person replacing the assay plate on one of its series of gauges. Each gauge in the series is authorized to contain up to 7.4 gigabecquerels (200 millicuries) of Cs-137. The manufacturer based its estimate on observations of individuals performing the recommended procedure according to good radiation safety practices. The manufacturer had the following types of information:

- Time needed to perform the entire procedure (e.g., 15 minutes)
- Expected dose rate received by the whole body of the individual, associated with the shielded source and determined using measured or manufacturer-determined data (e.g., 0.02 mSv/hr [2 mrem/hr] at 46 cm [18.1 in] from the shield)
- Time the hands were exposed to the shielded source (e.g., 6 min)
- Expected dose rate received by the extremities of the individual, associated with the shielded source and determined using measured or manufacturer-determined data on contact with the shield (e.g., 0.15 mSv/hr [15 mrem/hr])

From this information, the manufacturer estimated that the individual performing each routine cleaning and lubrication could receive the following:

- Less than 0.005 mSv (0.5 mrem) TEDE (whole body) and
- 0.015 mSv (1.5 mrem) to the hands.

The applicable TEDE (whole body) limit is 50 mSv (5 rems) per year and 10% of that value is 5 mSv (500 millirems) per year. If one routine maintenance procedure delivers 0.005 mSv (0.5 mrem), then an individual could perform 1,000 of these procedures each year and remain within 10% of the applicable limit. The applicable shallow-dose equivalent (SDE) (extremities) is 500 mSv (50 rems) per year and 10% of that value is 50 mSv (5 rems or 5000 millirems) per year. If one of routine maintenance procedure delivers 0.015 mSv (1.5 mrem), then an individual could perform 3,333 of these procedures each year and remain within 10% of the applicable limit.

Based on the above specific situation, no dosimetry is required if a worker performs fewer than 1,000 routine maintenance procedures per year.

Guidance to Licensees

Licensees who wish to demonstrate that they are not required to provide dosimetry to their workers need to perform prospective evaluations similar to that shown in the example above. The expected dose rates, times, and distances used in the above example may not be appropriate to individual licensee situations. In their evaluations, licensees need to use information appropriate to the type(s) of gauge(s) they intend to use; this information is generally available from the gauge manufacturer or the SSDR Certificate maintained by VDH, the NRC and other Agreement States. **Table 6** may be helpful in performing a prospective evaluation.

Licensees should review evaluations periodically and revise them as needed. Licensees need to check assumptions used in their evaluations to ensure that they continue to be up-to-date and accurate. For example, if workers become lax in following good radiation safety practices, perform the task more slowly than estimated, work with new gauges containing sources of different activities or radionuclides, or use modified procedures, the licensee would need to conduct a new evaluation.

Table 6. Dosimetry Evaluation

Dosimetry Evaluation for _____		Model _____	Gauge _____
A.	Time needed to perform the entire routine maintenance procedure.	_____ minutes/60	_____ hour
B.	Expected whole body dose rate received by the individual, determined using exposure rates measured on contact with the gauge while the sealed source is in the shielded position.	_____ mrem/hr	
C.	Time the <u>hands</u> were exposed to the shielded source.	_____ minutes/60	_____ hour
D.	Expected extremity dose rate received by the individual, determined using measured or manufacturer-provided data for the shielded source at the typical distance from the hands to the shielded source.	_____ mrem/hr	

Formula: (_____ # hours in Row A) x (_____ mrem/hr in Row B) = (_____ mrem per routine procedure) x (_____ # of routine maintenance procedures each year) = _____ mrem* Whole Body Dose

Formula: (_____ # hours in Row C) x (_____ mrem/hr in Row D) = (_____ mrem per routine procedure) x (_____ # of routine maintenance procedures each year) = _____ mrem ** Extremity Dose

* Expected whole Body Dose Less Than 500 mrem requires no dosimetry

** Expected Extremity Dose Less Than 5000mrem requires no dosimetry

Appendix K

Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

Licensees must ensure that:

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

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

2. The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.

Unrestricted areas may include offices, shops, laboratories, a nearby walkway, an area near the gauge that requires frequent maintenance, areas outside buildings, and nonradioactive equipment storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials. However, the licensee may control access to these areas for other reasons such as security.

Licensees must show compliance with both 1 and 2 above. Calculations or a combination of calculations and measurements (e.g., using an environmental TLD) are often used to prove compliance.

Calculation Method

For ease of use by most fixed gauge licensees, the examples in this appendix use conventional units. The conversions to SI units are as follows: 1 ft = 0.305 m; 1 mrem = 0.01 mSv.

The calculation method takes a tiered approach, going through a three-part process starting with a worst case situation and moving toward more realistic situations. It makes the following simplifications:

- each gauge is a point source;
- typical radiation levels encountered when the source is in the shielded position are taken from either the Sealed Source & Device Registration (SSDR) Certificate or the manufacturer's literature; and
- No credit is taken for any shielding found between the gauges and the unrestricted areas.

Part 1 of the calculation method is simple but conservative. It assumes that an affected member of the public is present 24 hours a day and uses only the inverse square law to determine if the distance between the gauge and the affected member of the public is sufficient to show compliance with the public dose limits. Part 2 considers not only distance, but also the time that the affected member of the public is actually in the area under consideration. Part 3 considers distance and the portion of time that both the gauge and the affected member of the public are present. Using this approach, licensees make only those calculations that are needed to

demonstrate compliance. In many cases licensees will need to use the calculation method through Part 1 or Part 2. The results of these calculations typically result in higher radiation levels than would exist at typical facilities, but provide a method for estimating conservative doses which could be received.

Example 1

To better understand the calculation method, we will look at ABC Bottling, Inc., a fixed gauge licensee. Yesterday, while on a walk-through during product changeover, the company's president noted that three new gauges will be very close to a bottling control panel where a quality control supervisor, a worker who does not work with fixed gauges, works. The company's president asked Joe, the Radiation Safety Officer (RSO), to determine if the company is complying with the VDH rule.

Joe measures the distances from each gauge to the bottling control panel and looks up in the manufacturer's literature the radiation levels individuals would encounter for each gauge. **Figure 1** is Joe's sketch of the areas in question, and **Table 7** summarizes the information Joe has on each gauge.

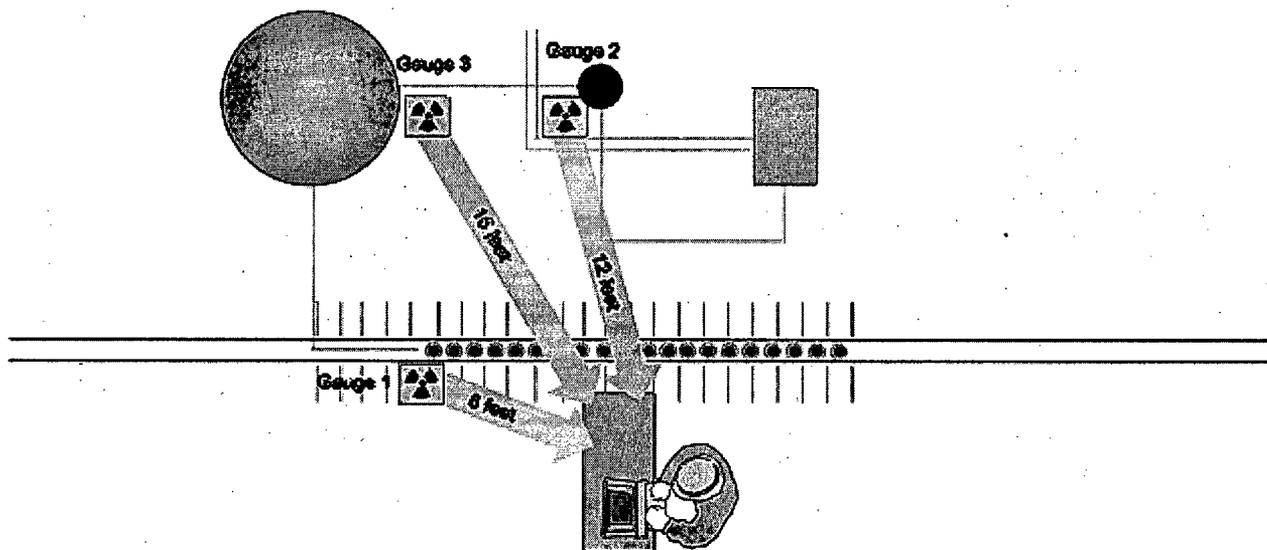


Figure 1. Diagram of Bottling Line and Fixed Gauges

Table 7. Information Known about Each Gauge

Description of Known Information	Gauge 1	Gauge 2	Gauge 3
Where gauge is located	Gauge on bottling line	Gauge on main feed line	Gauge on tank
Dose rate in mrem/hr encountered at specified distance from the gauge (from manufacturers literature)	2 mrem/hr at 1 ft	8 mrem/hr at 1 ft	2 mrem/hr at 3 ft
Distance in ft to bottling control panel	8 ft	12 ft	15 ft

Example 1: Part 1

Joe's first thought is that the distance between the gauges and the bottling control panel may be sufficient to show compliance with 12VAC5-481-720. So, taking a worst case approach, he assumes: 1) the gauges are constantly present (i.e., 24 hr/d), 2) all three gauges are on (i.e., shutters are open), and 3) a quality control (QC) supervisor, a worker who does not work with the fixed gauges, is constantly sitting at the control panel (i.e., 24 hr/d). Joe proceeds to calculate the dose the QC supervisor might receive hourly and yearly from each gauge as shown in Tables 8, 9, and 10 below.

Table 8. Calculation Method, Part 1: Hourly and Annual Dose Received from Gauge 1

Gauge 1			
Step No.	Description	Input Data	Results
1	Dose received in an hour at known distance from gauge (e.g., from manufacturer's data), in mrem/hr	2	2
2	Square of the distance (ft) at which the Step 1 rate was measured, in square feet	(1) ²	1
3	Square of the distance (ft) from the gauge to the bottling control panel in an unrestricted area, in square feet	(8) ²	64
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	2 x 1 = 2	
5	Divide the result of Step 4 by the result of Step 3 to calculate the dose received by the worker at the bottling control panel, HOURLY DOSE RECEIVED FROM GAUGE 1 , in mrem in an hour	2/64 = 0.031	
6	Multiply the result of Step 5 by 24 hr/d x 365 d/yr = MAXIMUM ANNUAL DOSE RECEIVED FROM GAUGE 1 , in mrem in a year.	0.031 x 24 x 365 = 0.031 x 8760 = 272	

Table 9. Calculation Method, Part 1: Hourly and Annual Dose Received from Gauge 2

Gauge 2			
Step No.	Description	Input Data	Results
1	Dose received in an hour at known distance from gauge (e.g., from manufacturer's data), in mrem/hr	8	8
2	Square of the distance (ft) at which the Step 1 rate was measured, in square feet	(1) ²	1
3	Square of the distance (ft) from the gauge to the bottling control panel in an unrestricted area, in square feet	(12) ²	144
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	8 x 1 = 8	
5	Divide the result of Step 4 by the result of Step 3 to calculate the dose received by the worker at the bottling control panel, HOURLY DOSE RECEIVED FROM GAUGE 2 , in mrem in an hour	8/144 = 0.056	
6	Multiply the result of Step 5 by 24 hr/d x 365 d/yr = MAXIMUM ANNUAL DOSE RECEIVED FROM GAUGE 2 , in mrem in a year.	0.056 x 24 x 365 = 0.056 x 8760 = 491	

Table 10. Calculation Method, Part 1: Hourly and Annual Dose Received from Gauge 3

Gauge 3			
Step No.	Description	Input Data	Results
1	Dose received in an hour at known distance from gauge (e.g., from manufacturer's data), in mrem/hr	2	2
2	Square of the distance (ft) at which the Step 1 rate was measured, in square feet	(3) ²	9
3	Square of the distance (ft) from the gauge to the bottling control panel in an unrestricted area, in square feet	(15) ²	225
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	2 x 9 = 18	
5	Divide the result of Step 4 by the result of Step 3 to calculate the dose received by the worker at the bottling control panel, HOURLY DOSE RECEIVED FROM GAUGE 3 , in mrem in an hour	18/225 = 0.08	
6	Multiply the result of Step 5 by 24 hr/d x 365 d/yr = MAXIMUM ANNUAL DOSE RECEIVED FROM GAUGE 3 , in mrem in a year.	0.08 x 24 x 365 = 0.08 x 8760 = 701	

To determine the total hourly and total annual dose received, Joe adds the pertinent data from the preceding tables.

Table 11. Calculation Method, Part 1: Total Hourly and Annual Dose Received from Gauges 1, 2, and 3

Step No.	Description	Gauge 1	Gauge 2	Gauge 3	Sum
7	TOTAL HOURLY DOSE RECEIVED from Step 5 of Tables 5, 6, and 7, in mrem in an hour	0.031	0.056	0.08	0.031 + 0.056 + 0.08 = 0.167
8	TOTAL ANNUAL DOSE RECEIVED from Step 6 of Tables 5, 6, and 7, in mrem in a year	272	491	701	272 + 491 + 701 = 1464

Note: The Sum in Step 7 demonstrates compliance with the 2 mrem in any one hour limit. Reevaluate if assumptions change. If the Sum in Step 8 exceeds 100 mrem/yr, proceed to Part 2 of the calculation method.

At this point, Joe is pleased to see that the total dose that an individual could receive in any one hour is only 0.167 mrem, but notes that an individual could receive a dose of 1,464 mrem in a year, much higher than the 100 mrem limit.

Example 1: Part 2

Joe reviews his assumptions and recognizes that the QC supervisor is not at the bottling control panel 24 hr/d. He decides to make a realistic estimate of the number of hours the QC supervisor would be present at the bottling control panel, keeping his other assumptions constant (i.e., the

gauges are constantly present (i.e., 24 hr/d), all three gauges remain on (i.e., shutter is open). He then recalculates the annual dose received.

Table 12. Calculation Method, Part 2: Annual Dose Received from Gauges 1, 2, and 3

Step No.	Description	Results
9	A. Average number of hours per day that individual spends in area of concern (e.g., worker present at bottling control panel 5 hr/day; the remainder of the day the worker is away from the area performing other duties that are not in the vicinity of gauges)	5
	B. Average number of days per week in area (e.g., worker is part time and works 3 days/week)	3
	C. Average number of weeks per year in area (e.g., worker works all year)	52
10	Multiply the results of Step 9.A. by the results of Step 9.B. by the results of Step 9.C. = AVERAGE NUMBER OF HOURS IN AREA OF CONCERN PER YEAR	$5 \times 3 \times 52 = 780$
11	Multiply the sum in Step 7 by the results of Step 10 = ANNUAL DOSE RECEIVED FROM GAUGES CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN, in mrem in a year	$0.167 \times 780 = 130$

Note: If Step 11 exceeds 100 mrem in a year, proceed to Part 3 of the calculation method.

Although Joe is pleased to note that the calculated annual dose received is significantly lower, he realizes it still exceeds the 100 mrem in a year limit.

Example 1: Part 3

Again Joe reviews his assumptions and recognizes that Gauge 3 will only be used on the process line during product changeovers and Gauge 2 has different radiation levels depending on whether the gauge is in the 'on' or 'off' position (i.e., shutter is open or closed). As he examines the situation, he realizes he must consider each gauge individually.

Table 13. Calculation Method, Part 3: Summary of Information

<p>INFORMATION ON GAUGES:</p> <ul style="list-style-type: none"> • Gauge 1: operates continuously (24 hrs/day) on the bottling line. • Gauge 2: operates (in the "on" position) while the tank is being filled, approximately 1 hour during the time the worker is present. When the pipe is not filling the tank, the gauge is in the "off" position. While in the "off" position, the radiation level around the gauge drops to 2 mrem/hr at 1 ft, one-fourth of the radiation level as when the gauge is in the "on" position. • Gauge 3: is only used on the process line during product changeovers, 4 weeks per year. While affixed, it operates continuously (24 hrs/day).
--

INFORMATION FROM EXAMPLE 1, PART 2, ON WHEN THE WORKER IS PRESENT AT THE BOTTLING CONTROL PANEL:

- 5 hours per day
- 3 days per week
- 52 weeks per year

Table 14. Calculation Method, Part 3: Annual Dose Received from Gauges 1, 2, and 3

Step No.	Description	Gauge 1	Gauge 2 'On'	Gauge 2 'Off'	Gauge 3
12	Average number of hours per day gauge operates when worker is present at the bottling control panel	5	1	4	5
13	Average number of days per week gauge operates when worker is present at the bottling control panel	3	3	3	3
14	Average number of weeks per year gauge operates when worker is present at the bottling control panel	52	52	52	4
15	Multiply the results of Step 12 by the results of Step 13 by the results of Step 14 = TOTAL HOURS EACH GAUGE OPERATED PER YEAR WHILE WORKER IS PRESENT AT BOTTLING CONTROL PANEL	$5 \times 3 \times 52 = 780$	$1 \times 3 \times 52 = 156$	$4 \times 3 \times 52 = 624$	$5 \times 3 \times 4 = 60$
16	Multiply the results of Step 15 by the results of Step 7 (for Gauge 2 in the "off" position, the radiation level drops to $1/4^{\text{th}}$, so divide the results of Step 7 by 4) = ANNUAL DOSE RECEIVED FROM EACH GAUGE, in mrem in a year	$780 \times 0.031 = 24$	$156 \times 0.056 = 8.7$	$624 \times (0.056/4) = 8.7$	$60 \times 0.08 = 4.8$ in mrem in a year
17	Sum the results of Step 16 for each gauge = TOTAL ANNUAL DOSE RECEIVED CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN AND TIME GAUGE OPERATES, in mrem in a year	$24 + 8.7 + 4.8 = 46.2$			

Note: If the result in Step 17 is greater than 100 mrem/yr, the licensee must take corrective actions.

Joe is pleased that the result in Step 17 shows compliance with the 100 mrem/yr limit. Had the result in Step 17 been higher than 100 mrem/yr, then Joe could have done one or more of the following:

- Consider whether the assumptions used to determine occupancy and the time each gauge operates are accurate, revise the assumptions as needed, and recalculate using the new assumptions
- Calculate the effect of any shielding located between the gauges and the bottling control panel -- such calculation is beyond the scope of this Appendix
- Take corrective action (e.g., add shielding, move the bottling control panel) and perform new calculations to demonstrate compliance
- Train the QC supervisor as required by **12VAC5-481-2270**.

Note that in the example, Joe evaluated the unrestricted area at the bottling control panel. Licensees also need to make similar evaluations for other unrestricted areas and to keep in mind the ALARA principle, taking reasonable steps to keep radiation dose received below regulatory requirements. In addition, licensees need to be alert to changes in situations (e.g., adding a gauge to the process line, changing the QC supervisor's schedule, or changing the estimate of the portion of time spent at the bottling control panel) and to perform additional evaluations, as needed.

RECORD KEEPING: 12VAC5-481-1050 requires licensees to maintain records demonstrating compliance with the dose limits for individual members of the public.

Combination Measurement - Calculation Method

This method, which allows the licensee to take credit for shielding between the gauge and the area in question, begins by measuring radiation levels in the areas, as opposed to using manufacturer-supplied rates at a specified distance from each gauge. These measurements must be made with calibrated survey meters sufficiently sensitive to measure background levels of radiation. A maximum dose of 1 mSv (100 mrem) received by an individual over a period of 2080 hours (i.e., a work year of 40 hr/wk for 52 wk/yr) is equal to less than 0.5 microsievert (0.05 mrem) per hour.

This rate is well below the minimum sensitivity of most commonly available G-M survey instruments.

Instruments used to make measurements for calculations must be sufficiently sensitive. An instrument equipped with a scintillation-type detector (e.g., NaI(Tl)) or a micro-R meter used in making very low gamma radiation measurements should be adequate.

Licensees may also choose to use environmental TLDs. TLDs used for personnel monitoring (e.g., LiF) may not have sufficient sensitivity for this purpose. Generally, the minimum reportable dose received is 0.1 mSv (10 mrem). Suppose a TLD monitors dose received and is changed once a month. If the measurements are at the minimum reportable level, the annual dose received could have been about 1.2 mSv (120 mrem), a value in excess of the 1 mSv/yr (100 rem/yr) limit. If licensees use TLDs to evaluate compliance with the public dose limits, they should consult with their TLD supplier and choose more sensitive TLDs, such as those containing CaF₂ that are used for environmental monitoring. This direct measurement method would provide a definitive measurement of actual radiation levels in unrestricted areas without

any restrictive assumptions. Records of these measurements can then be evaluated to ensure that rates in unrestricted areas do not exceed the 1 mSv/yr (100 mrem/yr) limit.

Example 2

As in Example 1, Joe is the RSO for ABC Bottling, Inc., a fixed gauge licensee. The company has three gauges located near a bottling control panel which is operated by a worker who does not work with the fixed gauges. See **Figure 1** and **Table 7** for information. Joe wants to see if the company complies with the public dose limits at the bottling control panel.

Joe placed an environmental TLD badge at the bottling control panel for 30 days. The TLD processor sent Joe a report indicating the TLD received 100 mrem.

Table 15. Combination Measurement - Calculation Method

Step No.	Description	Input Data and Results
Part 1		
1	Dose received by TLD, in mrem	100
2	Total hours TLD exposed	24 hr/d x 30 d/mo = 720
3	Divide the results of Step 1 by the results of Step 2 to determine HOURLY DOSE RECEIVED , in mrem in an hour	0.14
4	Multiply the results of Step 3 by 365 d/yr x 24 hr/d = 8760 hours in one year = MAXIMUM ANNUAL DOSE RECEIVED FROM GAUGES , in mrem in a year	365 x 24 x 0.14 = 8760 x 0.14 = 1226
<p>Note: For the conditions described above, Step 3 indicates that the dose received in any one hour is less than the 2 mrem in any one hour limit. However, if there are any changes, then the licensee would need to reevaluate the potential doses which could be received in any one hour. Step 4 indicates that the annual dose received would be much greater than the 100mrem in a year allowed by the regulations.</p>		
Part 2		
<p>At this point Joe can adjust for a realistic estimate of the time the worker spends at the bottling control panel as he did in Part 2 of Example 1.</p>		
Part 3		
<p>If the results of Joe's evaluation in Part 2 show that the annual dose received in a year exceeds 100 mrem, then he can make adjustments for realistic estimates of the time spent in the area of concern as in Part 3 of Example 1. (Recall that the TLD measurement was made while all the gauges were operating; i.e., 24 hr/d for the 30 days that the TLD was in place.)</p>		

Appendix L

Operating and Emergency Procedures

Operating and Emergency Procedures

Operating Procedures:

- If personnel dosimetry is provided:
 - Always wear your assigned film badge or optically simulated luminescent dosimeter (OSL) when using the gauge.
 - Never wear another person's film badge or OSL.
 - Never store your film badge or OSL near the gauge.
- Use the gauge according to the manufacturer's or distributors instructions and recommendations. Perform routine cleaning and maintenance according to the manufacturer's or distributor's instructions and recommendations.
- Test each gauge for the proper operation of the on-off mechanism (shutter) and indicator, if any, at intervals not to exceed 6 months or as specified in the SSDR certificate.
- Do not touch the unshielded source with your fingers, hands, or any part of your body.
- Do not place hands, fingers, feet, or other body parts in the radiation field from an unshielded source.
- Post a radiation warning sign at each entryway to an area where it is possible to be exposed to the beam.
- Prevent employees from entering the radiation beam during maintenance, repairs, or work in, on, or around the bin, tank, or hopper on which the device is mounted by developing lock-out procedures. These procedures should specify who will be responsible for ensuring that the lock-out procedures are followed.
- Prevent unauthorized access, removal, or use of the gauge.
- After making changes affecting the gauge (e.g., changing the location of gauges, removing shielding, adding gauges, changing the occupancy of adjacent areas), reevaluate compliance with public dose limits and ensure proper security of gauges.
- Conduct a physical inventory every 6 months to account for all sealed sources and devices.

Emergency Procedures:

- If the gauge becomes damaged or if any other emergency or unusual situation arises:
 - Stop use of the gauge.
 - Immediately secure the area and keep people away from the gauge until the situation is assessed and radiation levels are known. However, perform first aid

for any injured individuals and remove them from the area only when medically safe to do so.

- If any equipment is involved, isolate the equipment until it is determined there is no contamination present.
- Gauge users and other potentially contaminated individuals should not leave the scene until emergency assistance arrives.
- Notify the persons in the order listed below of the situation:

NAME	WORK PHONE NUMBER	HOME PHONE NUMBER
_____	_____	_____
_____	_____	_____

- Follow the directions provided by the person contacted above.

Note: Fill in with (and update, as needed) the names and telephone numbers of appropriate personnel (e.g., the RSO, AUs, or other knowledgeable licensee staff, licensee's consultant, gauge manufacturer, distributor or representative, fire department, or other emergency response organization, as appropriate, and the agency) to be contacted in case of emergency.

RSO and Licensee Management:

- Arrange for a radiation survey to be conducted as soon as possible by a knowledgeable person using appropriate radiation detection instrumentation. This person could be a licensee employee using a survey meter, a local emergency responder, or a consultant. To accurately assess the radiation danger, it is essential that the person performing the survey be competent in the use of the survey meter.
- Make necessary notifications to local authorities as well as the agency as required. **Appendix P** contains typical agency incident notifications required for fixed gauge licensees. (Even if not required to do so, you may report **ANY** incident to the agency by calling (804) 864-8150 during normal business hours. For immediate notifications after normal business hours, the 24 hour emergency telephone number is (804) 674-2400 or (800) 468-8892. Identify the emergency as radiological. VDH notification is required when gauges containing licensed material are lost or stolen and when gauges are damaged or involved in incidents that result in doses in excess of **12VAC5-481-1100** limits. Reporting requirements are found in **12VAC5-481-1110**.

Copies of operating and emergency procedures must be posted at each location of use or if posting procedures is not practicable, a notice that briefly describes the procedures and states where they may be examined may be posted instead.

Copies of operating and emergency procedures should be provided to all gauge users.

Appendix M

Model Leak Test Program

Model Leak Test Program

Training

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

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

- Principles and practices of radiation protection
- Radioactivity measurements, monitoring techniques, and the use of instruments
- Mathematics and calculations basic to the use and measurement of radioactivity
- Biological effects of radiation.

Appropriate on-the-job-training consists of:

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

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests will be analyzed in a low-background area.
- Individuals conducting leak tests will use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed.
- A NaI(Tl) well counter system with a single or multichannel analyzer or an equivalent detector will be used to count samples from gauges containing gamma-emitters (e.g., Cs-137, Co-60).
- A liquid scintillation or gas-flow proportional counting system or equivalent detector will be used to count samples from gauges containing beta-emitters (e.g., Sr-90) or alpha emitters (e.g., Am-241).

Frequency for Conducting Leak Tests of Sealed Sources

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

Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as gauge 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 microcurie) of the radionuclide contained in the gauge.
- Using the selected instrument count and record background count rate.

- Check the instrument's counting efficiency using standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within $\pm 5\%$ of the stated value and traceable to a primary radiation standard such as those maintained by the National Institutes of Standards and Technology (NIST).
- Calculate efficiency.

For example:

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

Where:

- cpm = counts per minute
- std = standard
- bkg = background
- Bq = Becquerel

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

For example:

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

- Sign and date the list of sources, data and calculations. Retain records for 3 years.
- If the wipe test activity is 185 Bq (0.005 microcurie) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly. Also notify the agency.

Reference: See the NRC webpage at <http://www.nrc.gov> to obtain a copy of Draft RG FC 412-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Leak-Testing Services", dated June 1985.

Appendix N

Information Needed to Support Applicant's Request to Perform Non-Routine Operations

Information Needed to Support Applicant's Request to Perform Non-Routine Operations

Applicants should review the section in this document on 'maintenance', which discusses, in general, licensee responsibilities before any maintenance or repair is performed.

Non-routine operations include installation of the gauge, initial radiation survey, repair or maintenance involving or potentially affecting components, including electronics, related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding), gauge relocation, replacement, and disposal of sealed sources, alignment, removal of a gauge from service, and any other activities during which personnel could receive radiation doses exceeding VDH limits.

Any non-manufacturer/non-distributor supplied replacement components or parts, or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer or distributor need to be evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration. Licensees also need to ensure that, after maintenance or repair is completed, the gauge is tested and functions as designed, before the unit is returned to routine use.

If non-routine operations are not performed properly with attention to good radiation safety principles, the gauge may not operate as designed and personnel performing these tasks could receive radiation doses exceeding VDH limits. Radionuclides and activities in fixed gauges vary widely. For illustrative purposes in less than one minute, an unshielded cesium-137 source with an activity of 100 millicuries can deliver 0.05 Sv (5 rems) to a worker's hands or fingers (i.e., extremities), assuming the extremities are 1 centimeter from the source. However, gauges can contain sources of even higher activities with correspondingly higher dose rates. The threshold for extremity monitoring is 0.05 Sv (5 rems) per year.

Thus, applicants wishing to perform non-routine operations must use personnel with special training and follow appropriate procedures consistent with the manufacturer's or distributors instructions and recommendations that address radiation safety concerns (e.g., use of radiation survey meter, shielded container for the source, and personnel dosimetry (if required)).

Accordingly, provide the following information:

Describe the types of work, maintenance, cleaning, repair that involve:

- Installation, relocation, or alignment of the gauge
- Components, including electronics, related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding)
- Replacement and disposal of sealed sources
- Removal of a gauge from service
- A potential for any portion of the body to come into contact with the primary radiation beam; or
- Any other activity during which personnel could receive radiation doses exceeding VDH limits.

The principal reason for obtaining this information is to assist in the evaluation of the qualifications of individuals who will conduct the work and the radiation safety procedures they will follow.

A licensee may initially mount a gauge, without specific VDH, the NRC or another Agreement State authorization, if the gauge's SADR Certificate explicitly permits mounting of gauges by users and under the following conditions:

- The gauge must be mounted according to written instructions provided by the manufacturer or distributor;
- The gauge must be mounted in a location compatible with the "*Conditions of Normal Use*" and "*Limitations and/or Other Considerations of Use*" in the certificate of registration issued by NRC or another Agreement State;
- The on-off mechanism (shutter) must be locked in the off position, if applicable, or the source must be otherwise fully shielded;
- The gauge must be received in good condition (package was not damaged); and
- The gauge must not require any modification to fit in the proposed location.

Mounting does not include electrical connection, activation, or operation of the gauge. The source must remain fully shielded and the gauge may not be used until it is installed and made operational by a person specifically licensed by VDH, the NRC or another Agreement State to perform such operations.

- Identify who will perform non-routine operations and their training and experience. Acceptable training would include manufacturer's or distributor's courses for non-routine operations or equivalent.
- Submit procedures for non-routine operations. These procedures should ensure the following:
 - doses to personnel and members of the public are within regulatory limits and ALARA (e.g., use of shielded containers or shielding);
 - the source is secured against unauthorized removal or access or under constant surveillance;
 - appropriate labels and signs are used;
 - manufacturer's or distributor's instructions and recommendations are followed;
 - any non-manufacturer/non-distributor supplied replacement components or parts, or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer or distributor are evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration; and
 - before being returned to routine use, the gauge is tested to verify that it functions as designed and source integrity is not compromised.
 - Confirm that individuals performing non-routine operations on gauges will wear both whole body and extremity monitoring devices or perform a prospective evaluation demonstrating that unmonitored individuals performing non-routine operations are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits.
- Verify possession of at least one survey instrument that meets the criteria in 'Survey Instruments' in VAREG 'Guidance for Fixed Gauge Devices'.

- Describe steps to be taken to ensure that radiation levels in areas where non-routine operations will take place do not exceed **12VAC5-481-720** limits. For example, applicants can do the following:
 - commit to performing surveys with a survey instrument (as described above);
 - specify where and when surveys will be conducted during non-routine operations; and
 - commit to maintaining, for 3 years from the date of the survey, records of the survey (e.g., who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements), as required by **12VAC5-481-1050**.

Appendix O

Major DOT Regulations; Sample Shipping Documents, Placards and Labels

Major DOT Regulations; Sample Shipping Documents, Placards and Labels

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

- Hazardous Materials Table, **49 CFR 172.101**, Appendix A, list of hazardous substances and reportable quantities (RQ), Table 2: radionuclides
- Shipping Papers **49 CFR 172.200, 172.201, 172.202, 172.203, 172.204**: general entries, description, additional description requirements, shipper's certification
- Package Markings **49 CFR 172.300, 172.301, 172.303, 172.304, 172.310, 172.324**: General marking requirements for non-bulk packagings, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging
- Package Labeling **49 CFR 172.400, 172.401, 172.403, 172.406, 172.407, 172.436, 172.438, 172.440**: General labeling requirements, prohibited labeling, radioactive materials, placement of labels, specifications for radioactive labels
- Placarding of Vehicles **49 CFR 172.500, 172.502, 172.504, 172.506, 172.516, 172.519, 172.556**: Applicability, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, specifications for RADIOACTIVE placards
- Emergency Response Information, Subpart G, **49 CFR 172.600, 172.602, 172.604**: Applicability and general requirements, emergency response information, emergency response telephone number
- Training, Subpart H, **49 CFR 172.702, 172.704**: Applicability and responsibility for training and testing, training requirements
- Radiation Protection Program for Shippers and Carriers, Subpart I, **49 CFR 172.801, 172.803, 172.805**: Applicability of the radiation protection program, radiation protection program, recordkeeping, and notifications
- Shippers - General Requirements for Shipments and Packaging, Subpart I, **49 CFR 173.403, 173.410, 173.412, 173.415, 173.431, 173.433, 173.435, 173.441, 173.443, 173.448, 173.475, 173.476**: Definitions, general design requirements, additional design requirements for Type A packages, authorized Type A packages, activity limits for Type A packages, requirements for determining A1 and A2, table of A1 and A2 values for radionuclides, radiation level limitations, contamination control, general transportation requirements, quality control requirements prior to each shipment, approval of special form radioactive materials
- Carriage by Public Highway - General Information and Regulations, Subpart A, **49 CFR 177.816, 177.817, 177.834(a), 177.842**: Driver training, shipping paper, general requirements (secured against movement), Class 7 (radioactive) material.

Note: Type B shipping packages transport quantities of radionuclides greater than Type A allowable quantities. Requirements for Type B packages are in **12VAC5-481-3000**.

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.

- Labeling is required to be: (1) placed near the required marking of the proper shipping name, (2) printed or affixed to the package surface, (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.
- Two labels are required on opposite sides of the package, excluding the bottom.

Determination of Required Label

Size: Sides: ≥ 100 mm Border: 5-6.3 mm			
	49 CFR 172.436 WHITE-I	49 CFR 172.438 YELLOW-II	49 CFR 172.440 YELLOW-III
Required when:	Surface radiation level ≤ 0.005 mSv/hour (0.5 mrem/hour)	0.005 mSv/hour (0.5 mrem/hour) < surface radiation level ≤ 0.5 mSv/hour (50 mrem/hour)	0.5 mSv/hour (50 mrem/hour) < surface radiation level ≤ 2 mSv/hour (200 mrem/hour)
Or:	TI = 0 [1 meter dose rate < 0.5 mrem/hour]	TI ≤ 1 [1 meter dose rate ≤ 1 mrem/hour]	1 < TI ≤ 10 [1 meter dose rate ≤ 10 mrem/hour]

Content on Radioactive Labels

RADIOACTIVE label must contain (entered using a durable, weather-resistant means):

- (1) The radionuclides in the package. Symbols (e.g., Ir-192) 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.
- (3) The Transport Index (TI) in the supplied box. The TI is entered only on YELLOW-II and YELLOW-III labels.

Some Special Considerations for Labeling Requirements

- Radioactive material, excepted packages (e.g., Limited Quantity, Radioactive Instrument and Article) are excepted from labeling.
- The “Cargo Aircraft Only” label is typically required for radioactive materials packages shipped by air [§172.402(c)]

Appendix P

VDH Incident Notifications

VDH Incident Notifications

Table 16. Typical VDH Incident Notifications Required for Fixed Gauge 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	12VAC5-481-1110
Extremity dose greater than 2.5 Sv (250 rems)	Immediate	30 days	12VAC5-481-1110
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
Whole body dose greater than 0.05 Sv (5 rems)	None	30 days	12VAC5-481-1110
Dose to individual member of the public greater than 1mSv (100 mrems)	None	30 days	12VAC5-481-1110
Filing petition for bankruptcy	None	Immediately after filing petition	12VAC5-481-500 E & F
Expiration of License	None	60 days	12VAC5-481-510 D
Decision to permanently cease licensed activities at entire site	None	60 days	12VAC5-481-510 D
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 D
No principal activities conducted for 24 months at the entire site	None	60 days	12VAC5-481-510 D
No principle activities conducted for 24 months in any separate building or outdoor area that is unsuitable for release for unrestricted used	None	60 days	12VAC5-481-510 D
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	Immediate	30 days	12VAC5-481-1100 12VAC5-481-1110

Event	Telephone Notification	Written Report	Regulatory Requirement
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	12VAC5-481-1110
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	12VAC5-481-1110

Note: Telephone notifications shall be made to the agency at (804) 864-8150 during business hours and (804) 674-2400 or (800) 468-8892 after business hours. Identify the emergency as radiological.

Commonwealth of Virginia
Radiation Protection Regulatory Guide



**Guidance for Self-Shielded
Irradiators**

EPI-720 D

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

EXECUTIVE SUMMARY

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

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

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

This VAREG ‘Guidance for Self-Shielded Irradiators’ has been developed to streamline the application process for a Self-Shielded Irradiator License. A copy of the VDH Form, ‘Application for Radioactive Material License Authorizing the Use of Self-Shielded Irradiators’ is located in **Appendix A** of this guide.

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

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

In summary, the applicant will need to do the following to submit an application for a Self-Shielded Irradiator license:

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

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

Please identify all attachments with the applicant's name and license number (if a renewal).

- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original signed application along with attachments (if any).
- Submit the application fee (for new licenses only).
- Retain one copy of the licensee application and attachments (if any) for your future reference. You will need this information because the license will require that radioactive material be possessed and used in accordance with statements, representation, and procedures provided in the application and supporting documentation.

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

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ABBREVIATIONS

ALARA	as low as is reasonably achievable
ALI	annual limit on intake
ANSI	American National Standards Institute
AU	authorized user
bkg	background
Bq	Becquerel
CaF ₂	calcium fluoride
cc	centimeter cubed
CDE	committed dose equivalent
CEDE	committed effective dose equivalent
CFR	Code of Federal Regulations
Ci	Curie
CD-ROM	compact disc-read only memory
C/kg	coulomb/kilogram
cm ²	centimeter squared
Co-60	cobalt-60
cpm	counts per minute
Cs-137	cesium-137
d	Day
DOE	United States Department of Energy
DOT	United States Department of Transportation
dpm	disintegrations per minute
EDE	effective dose equivalent
FDA	United States Food and Drug Administration
ft	Foot
GBq	Gigabecquerel
G-M	Geiger-Mueller
GPO	Government Printing Office
hr	Hour
IN	Information Notice
IP	Inspection Procedure
kg	kilogram
LiF	lithium fluoride
m	meter
MBq	megabecquerel
mCi	millicurie
MeV	million electron volt
mGy	milligray
mo	Month
MOU	memorandum of understanding
mR	milliroentgen
mrem	millirem
mSv	millisievert
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	United States Nuclear Regulatory Commission
NTIS	National Technical Information Service
NVLAP	National Voluntary Laboratory Accreditation Program

OSL	optically stimulated luminescence dosimeters
OSP	Office of State Programs
P&GD	Policy and Guidance Directive
QA	quality assurance
R	roentgen
Rev.	revision
RG	Regulatory Guide
RQ	reportable quantities
RSO	radiation safety officer
SDE	shallow-dose equivalent
Sr-90	strontium-90
SFPO	Spent Fuel Project Office
SI	International System of Units (abbreviated SI from the French Le Systeme Internationale d'Unites)
SSD	sealed source and device
SSDR	Sealed Source and Device Registration
std	Standard
Sv	Sievert
TAR	technical assistance request
TBq	Terabecquerel
TEDE	total effective dose equivalent
TI	transportation index
TLD	thermoluminescent dosimeters
URL	uniform resource locator
U. S. C.	United States Code
USDA	United States Department of Agriculture
VAREG	Virginia Regulatory Guidance
VDH	Virginia Department of Health
wk	Week
yr	Year
μ Ci	microcurie
%	percent

PURPOSE OF GUIDE

This document provides guidance to an applicant preparing a license application for Self-Shielded Irradiator License. It also provides guidance on VDH's criteria for evaluating a Self-Shielded Irradiator license application. It is not intended to address the research and development or the commercial aspects of manufacturing, distribution, and service of self-shielded irradiators and their associated sources. Within this document, the phrases or terms, 'self-shielded irradiator', 'self-contained irradiators', or 'irradiators' are used interchangeably.

Note: Irradiators subject to the requirements of 12VAC5-481 'Virginia Radiation Protection Regulations' Part VII, 'Radiation Safety Requirements for Irradiators' are not discussed in this guide.

Irradiators are used for a variety of purposes in research, industry, and other fields resulting in different types for specific uses. Typical uses are:

- Irradiating blood or blood products
- Sterilizing or reducing microbes in medical and pharmaceutical supplies
- Preserving foodstuffs
- Studying radiation effects
- Synthesizing and modifying chemicals and polymers
- Eradicating insects through sterile male release programs
- Calibrating thermoluminescent dosimeters (TLDs).

The American National Standards Institute (ANSI) has developed and published safety standards for gamma irradiators. In determining basic safety requirements, ANSI divided all gamma irradiators into four general categories. This report deals with the type of irradiator discussed in ANSI Standard N433.1, "*Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiators (Category I)*".

Note: Copies of this standard may be ordered electronically at <http://www.ansi.org> or by writing to ANSI, 1430 Broadway, New York, NY 10018. Copies are also available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161 (1-800-533-6847).

This guide also uses the same definition of a self-shielded irradiator as the ANSI definition for a Category I irradiator: "*[a]n irradiator in which the sealed source(s) is completely contained in a dry container constructed of solid materials, the sealed source(s) is shielded at all times, and human access to the sealed source(s) and the volume(s) undergoing irradiation is not physically possible in its designed configuration.*"

Depending on the design, the radiation source within the irradiator may be in a fixed position or may be movable. In the latter case, interlocks are used to ensure that the source does not move into a position that, during normal use of the irradiators, may cause a radiation hazard to any individual. Bypassing or failure of an interlock could cause persons to be exposed to high levels of radiation.

Self-shielded irradiators typically contain several hundred to several thousand terabecquerels (TBq) (or curies (Ci)) of cesium-137 (Cs-137) or cobalt-60 (Co-60) and range in weight from several hundred to several thousand kilograms (kg) (or pounds). Other irradiators contain megabecquerel (MBq) (or millicurie (mCi)) quantities of strontium-90 (Sr-90), a beta emitter, and are used primarily for thermoluminescent dosimeter (TLD) calibration.

This guide identifies the information needed to complete VDH Form, 'Application for Radioactive Material License Authorizing the Use of Self-Shielded Irradiators.' (**Appendix A**).

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

- **Rule** - references 12VAC5-481 'Virginia Radiation Protection Regulations' requirements applicable to the item;
- **Criteria** - outlines the criteria used to judge the adequacy of the applicant's response;
- **Discussion** - provides additional information on the topic sufficient to meet the needs of most readers; and
- **Response from Applicant** - shows the appropriate item on the application and provides: response(s), offers the option of an alternative response, or indicates that no response is needed on that topic.

The information submitted in the application must be sufficient to demonstrate that proposed equipment, facilities, personnel, and procedures are adequate to protect the health and safety of the citizens of the Commonwealth of Virginia in accordance with agency guidelines.

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

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

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

This VAREG provides the latest guidance and is modeled on the Nuclear Regulatory Commission's (NRC) NUREG 1556, Volume 5. The VAREG shows the requirements in terms of the **12VAC5-481 'Virginia Radiation Protection Regulations'** and provides a user-friendly format to assist with the preparation of a Self-Shielded Irradiator license application.

LICENSES

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

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

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

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

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

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

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

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

WHO REGULATES AT FACILITIES IN THE COMMONWEALTH OF VIRGINIA?

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

Table 1: Who Regulates the Activity?

Applicant and Proposed Location of Work	Regulatory Agency
Federal agency regardless of location (except that Department of Energy [DOE] and, under most circumstances, its prime contractors are exempt from licensing [10 CFR 30.12])	NRC
Non-federal entity in non-Agreement State, U.S. territory, or possession	NRC
Non-federal entity in 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 VA at federally-controlled site subject to exclusive federal jurisdiction	NRC

Note: 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 and application;
- Compliance with current VDH and United States Department of Transportation (DOT) regulations and the licensee's operating and emergency procedures;
- Provision of adequate resources (including space, equipment, personnel, time and, if needed, contractors) to the radiation protection program to ensure that public, and workers are protected from radiation hazards;
- Appointment of a qualified individual who has agreed in writing to work as the RSO;

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

APPLICABLE RULE

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

The following parts of **12VAC5-481, 'Virginia Radiation Protection Regulations'** contain requirements applicable to Self-Shielded Irradiators licensees:

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

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

<http://www.vdh.virginia.gov/Epidemiology/RadiologicalHealth/>.

HOW TO FILE

Applicants for a materials license should do the following:

- Be sure to use the current guidance from VDH in preparing an application.
- Complete VDH Form, 'Application for Radioactive Material License Authorizing the Use of Self-Shielded Irradiators' (**Appendix A**).
- For each separate sheet, other than submitted with the application, identify and key it to the item number on the application, or the topic to which it refers.
- Submit all documents on 8 ½ x 11 inch paper.
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original, signed application.
- Retain one copy of the license application for your future reference.

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

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

WHERE TO FILE

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

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

LICENSE FEES

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

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

Direct all questions about VDH's fees or completion of **Item 11** of VDH Form, 'Application for Radioactive Material License Authorizing the Use of Self-Shielded Irradiators' (**Appendix A**) to: **Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, Virginia 23219** or **(804) 864-8150**.

CONTENTS OF APPLICATION

Item 1: Type of Application

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

Response from Applicant:

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

Item 2: Name and Mailing Address of Applicant

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

Notify the agency of changes in mailing address.

Response from Applicant:

Item 2 Name And Mailing Address Of Applicant: Applicant's Telephone Number (Include area code):
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Note: The agency must be notified before control of the license is transferred or when bankruptcy proceedings have been initiated. See below for more details. NRC Information Notice (IN) 97-30, "Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises", dated June 3, 1997, discusses the potential for the security and control of licensed material to be compromised during periods of organizational instability.

References: NRC Information Notices (IN) are available at NRC's web site, <http://www.nrc.gov>.

Timely Notification of Transfer of Control

Rule: 12VAC5-481-330, 12VAC5-481-500 B

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

Discussion: Transferring control may be the result of mergers, buyouts, or majority stock transfers. Although it is not the VDH's intent to interfere with the business decisions of

licensees, it is necessary for licensees to obtain prior agency written consent before the transaction is finalized. This is to ensure the following:

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

Notification of Bankruptcy Proceedings

Rule: 12VAC5-481-500 E & F

Criteria: Immediately following filing of voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify VDH, in writing, identifying the bankruptcy court in which the petition was filed and the date of filing.

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

Item 3: Person to Be Contacted Regarding Application

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

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

Response from Applicant:

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

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

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

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

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

A VDH approved license amendment is required before locating an irradiator at an address not already listed on the license or at a new room location, whether that irradiator is an additional unit or a relocation of an existing unit.

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; a local ordinance requiring registration of a radiation-producing device).

Response from Applicant:

Item 4 Addresses Where Licensed Material Will Be Used or Possessed (Do not use Post Office Box):	
Address	Telephone Number (Include area code)
Address	Telephone Number (Include area code)
Address	Telephone Number (Include area code)

Note: As discussed later under 'Financial Assurance and Record Keeping for Decommissioning', licensees do need to maintain permanent records on where licensed material was used or stored while the license was in force. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). For self-shielded irradiator licensees, acceptable records are sketches or written descriptions of the specific locations where each irradiator is used or stored and any information relevant to damaged devices or leaking radioactive sources.

Item 5: Radiation Safety Officer (RSO)

Rule: 12VAC5-481-450 A, 12VAC5-481-630

Criteria: RSOs must have adequate training and experience. Successful completion of training as described in **Appendix G** is evidence of adequate training and experience.

Discussion: The person responsible for the radiation protection program is called the Radiation Safety Officer (RSO). The RSO needs independent authority to stop operations that he or she considers unsafe. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. Typical RSO duties are provided in **Table 2** and described in **Appendix H**. VDH requires the name of the RSO on the license to ensure that licensee management has always identified a responsible, qualified person and that the named individual knows of his or her designation as RSO.

Table 2. RSO Duties and Authorities

Radiation Safety Officer Duties and Authorities
1. Establish and oversee all operating, emergency, and ALARA procedures and review them regularly.
2. Oversee all material disposals for compliance with VDH/DOT rules.
3. Ensure required inventories, leak tests, etc are conducted and the records are recorded and maintained.
4. Ensure irradiator security is maintained.
5. Operations are conducted safely and corrective actions are implemented, when necessary, including terminating operations.
6. Make certain all required routine maintenance is performed and operations and equipment are used properly.
7. Perform annual audit and notify appropriate parties if any item is found to be not in compliance with VDH rule.
Above all, the RSO is the key to maintaining the radiation safety of the operations to the workers, the public, and the environment.

Response from Applicant:

<p>Item 5. Radiation Safety Officer (RSO) (Check one box and attach evidence of training and experience)</p> <p>Name: _____ Telephone Number (Include area code): _____</p> <p><input type="checkbox"/> Before obtaining radioactive material, the proposed RSO will have successfully completed training as described in Appendix G of VAREG 'Guidance For Self-Shielded Irradiators'. Before being named as the RSO, future RSOs will have successfully completed training as described in Appendix G of VAREG 'Guidance For Self-Shielded Irradiators'.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> Alternative information demonstrating that the proposed RSO is qualified by training and experience is attached. Before being named as the RSO, future RSOs will have successfully completed training as described in Appendix G of VAREG 'Guidance For Self-Shielded Irradiators'.</p>

Note: It is important to notify the agency as soon as possible, of changes in the designation of the RSO.

Alternative responses will be evaluated using the criteria listed above.

Item 6: Authorized Users

Rule: 12VAC5-481-450 A, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-1100, 12VAC5-481-2260, 12VAC5-481-2270, 12VAC5-481-2310

Criteria: Authorized users (AUs) must have adequate training and experience. Successful completion of training as described in **Appendix G** is evidence of adequate training and experience.

Discussion: An AU is a person whose training and experience meet VDH criteria, who is named either explicitly or implicitly on the license, and who uses or directly supervises the use of licensed material. AUs must ensure the proper use, security, and routine maintenance of self-shielded irradiators containing licensed material. They must have appropriate training to provide reasonable assurance that they will use the irradiator safely, maintain security of and access to the irradiator, and respond appropriately to accidents and malfunctions.

An AU is considered to be supervising the use of licensed material when he or she directs personnel in operations involving the material. Although the AU may delegate specific tasks to supervised users (e.g., maintaining records), he or she is still responsible for safe use of licensed material.

Response from Applicant:

Item 6 Authorized Users (Check one box)

Before using radioactive material, authorized users will have received training as described in Appendix G in VAREG 'Guidance for Self-Shielded Irradiators'.

OR

A description of the training and experience for proposed authorized users is attached.

Item 6.1: Training for Individuals Working in or Frequenting Restricted Areas (Instructions to Occupationally Exposed Workers and Ancillary Personnel)

Rule: 12VAC5-481-450, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-2260, 12VAC5-481-2270, 12VAC5-481-2280, 12VAC5-481-2310

Criteria: Individuals working with, as well as in the vicinity of, a self-shielded irradiator must have adequate training and experience. For those individuals who are not AUs yet work in the vicinity of a self-shielded irradiator and, in the course of employment, are likely to receive in a year an occupational dose of radiation over 1 millisievert (mSv) (100 millirem (mrem)), the licensee must provide training as required by **12VAC5-481-2270**. The extent of this training must be commensurate with potential radiological health protection problems present in the work place.

Discussion: Individuals, other than AUs (e.g., biomedical engineers), may perform routine maintenance on irradiators. However, they must be trained in radiation safety and in the irradiator manufacturers' operating procedures, or they must work under the supervision and in the direct physical presence of someone who has this training.

Some licensees may have specific individuals trained to perform installations, relocations, non-routine maintenance, or repairs. Authorizations for these functions are separate from those for an AU or an individual who performs routine maintenance and will be specifically stated in a license condition. **Appendix I** contains training for individuals who will conduct non-routine maintenance.

A licensee may recognize that some individuals (e.g., housekeeping staff), although not likely to receive doses over 1 mSv (100 mrem), should receive training to ensure adequate security and control of licensed material. Licensees may provide these individuals with training commensurate with their involvement with licensed material. For example, housekeeping staff may receive training on the nature and location of the irradiator and the meaning of the radiation symbol, and instructions not to touch the irradiator and to remain out of the room if the irradiator door is open.

Item 7: Radioactive Material

Sealed Radioactive Material

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

Criteria: Applicants must provide the manufacturer's (or distributor's) name and model number for each requested sealed source and device. Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by NRC or another Agreement State.

Discussion: NRC or other Agreement States perform a safety evaluation of self-shielded irradiators before authorizing a manufacturer (or distributor) to distribute the irradiators to specific licensees. The safety evaluation is documented in a Sealed Source and Device Registration (SSDR) Certificate. Before the formalization of the SSDR process, some older irradiators may have been specifically approved on a license. Licensees can continue to use those units specifically listed on their licenses. Applicants must provide the manufacturer's (or distributor's) name and model number for each requested sealed source and device so that the agency can verify that they have been evaluated in an SSDR Certificate or specifically approved on a license.

As explained in an "*Urgent Notice*" with an enclosed Order, both dated July 3, 1984 (see **Appendix E**), an NRC licensee identified a malfunction that could have resulted in a radiation overexposure. The malfunction involved an interlock mechanism that would have failed to prevent a shielded door from being opened after the source had moved out of the shielded position. The Order, which remains in effect, modifies licenses that authorize J. L. Shepherd Mark I or Model 81-22 irradiators. Applicants wishing to use either of these models must comply with the Order's requirements.

Consult with the proposed manufacturer (or distributor) to ensure that requested sources and devices are compatible 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. Such changes may necessitate a custom registration review to be conducted by NRC or another Agreement State; increasing the time needed to process a licensing action.

SSDR Certificates contain sections on "*Conditions of Normal Use*" and "*Limitation and Other Considerations of Use*". These sections may include limitations derived from conditions imposed by the manufacturer (or distributor), by particular conditions of use that would reduce radiation safety of the device, or by circumstances unique to the sealed source or device. For example, working life of the device or appropriate temperature and other environmental conditions may be specified. Except as specifically approved by VDH, licensees are required to use irradiators according to their respective SSDR 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 SSDR.

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

Purpose(s) for Which Licensed Material Will Be Used

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

Criteria: Proposed activity is authorized by 12VAC5-481 'Virginia Radiation Protection Regulations', and irradiators will be used only for the purposes for which they were designed and according to the manufacturer's (or distributor's) recommendations and instructions for use as specified in an approved SSDR Certificate. Uses other than those already listed must not compromise the integrity of the source or source shielding or other components of the device critical to radiation safety.

Discussion: Allowed uses normally include irradiation of blood, insects, animals, biological samples, and inanimate objects. Usually prohibited are irradiation of flammable and explosive materials which may harm the shielding or the sealed source containment, or other materials (e.g., unsealed containers of acids or corrosive liquids) which may interfere with the safe operation of the device. Irradiation of food for commercial distribution to the public is subject to regulations of the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) and will not be discussed in this document.

Requests to irradiate items not listed or prohibited in the SSDR Certificate will be reviewed on a case-by-case basis. Applicants need to submit enough information to demonstrate that irradiation of the proposed items will not compromise the integrity of the source or source shielding, or other components critical to radiation safety of the device. Contact the agency for additional case-specific guidance. Being granted a VDH license does not relieve a licensee from complying with other applicable federal, state, or local regulations (e.g., FDA and USDA regulations about irradiation of food for commercial distribution).

Response from Applicant

Item 7 Radioactive Material (Attach additional pages if necessary) ELEMENT AND MASS NUMBER <input type="checkbox"/> Cobalt-60 <input type="checkbox"/> Cesium-137 <input type="checkbox"/> Strontium-90 <input type="checkbox"/> Other Isotope (please specify):	
SEALED SOURCE MANUFACTURER OR DISTRIBUTOR AND MODEL NUMBER	DEVICE MANUFACTURER OR DISTRIBUTOR AND MODEL NUMBER
MAXIMUM QUANTITY (Not to exceed either the maximum activity per source or device as specified in the Sealed Source and Device Registration Certificate)	INTENDED USE:

Note: For more information about the SSDR process, see the current version of NUREG - 1556, Vol. 3, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration". It can be accessed at NRC's web site, <http://www.nrc.gov>.

Item 7.1 Financial Assurance and Recordkeeping for Decommissioning

Rule: 12VAC5-481-100, 12VAC5-481-450 C, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-1161

Criteria: Self-shielded irradiator licensees authorized to possess sealed sources containing radioactive material in excess of the limits specified in 12VAC5-481-450 C must provide evidence of financial assurance for decommissioning.

Even if no financial assurance is required, licensees are required to maintain, in an identified location, decommissioning records related to structures and equipment where irradiators are used or stored and to leaking sources. Pursuant to 12VAC5-481-450 C, licensees must transfer these records important to decommissioning to either of the following:

- The new licensee, before licensed activities are transferred or assigned according to 12VAC5-481-500 B.
- The agency before the license is terminated.

Discussion: The requirements for financial assurance are specific to the types and quantities of radioactive material authorized on a license. Most self-shielded irradiator applicants and licensees do not need to take any action to comply with the financial assurance requirements because their total inventory of licensed material does not exceed the limits in 12VAC5-481-450 C. The limits for typical self-shielded irradiator sealed sources are shown in **Table 3**. Applicants requesting more than one radionuclide need to use the sum of the ratios method to determine whether financial assurance is needed. See **Appendix F** for additional information.

Table 3. Minimum Inventory Quantity Requiring Financial Assurance

Radionuclide	Activity	
	Gigabecquerel (GBq)	Curie (Ci)
Cs-137	3.7×10^6	100,000
Co-60	3.7×10^5	10,000
Sr-90	3.7×10^4	1,000

Applicants and licensees wanting to possess self-shielded irradiators or irradiators and other licensed materials exceeding the limits in 12VAC5-481-450 C must submit evidence of financial assurance or a decommissioning funding plan (12VAC5-481-450 C). NRC Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72", dated June 1990, contains approved wording for each mechanism authorized by the regulation to guarantee or secure funds except for the Statement of Intent for government licensees. See **Appendix F** for the recommended wording for a Statement of Intent.

VDH will authorize possession exceeding the limits shown in **Table 3**, without requiring decommissioning financial assurance, for the purpose of normal source exchange for no more than 30 days.

12VAC5-481-450 C also requires that licensees maintain records important to decommissioning in an identified location. All self-shielded irradiator licensees need to maintain records of structures and equipment where each irradiator 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 description of the area) concerning the specific areas and locations. If no records exist regarding structure and equipment where self-shielded irradiators 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 self-shielded irradiator licensees have experienced unusual occurrences (e.g., leaking sources, other incidents that involve spread of contamination), they also need to maintain records about contamination that remains after cleanup or that may have spread to inaccessible areas.

For self-shielded irradiator licensees whose sources have never leaked, acceptable records important to decommissioning are sketches or written descriptions of the specific locations where each irradiator was used or stored.

Requirements for Disposition of Records Important to Decommissioning

- Before licensed activities are transferred or assigned according to **12VAC5-481-500 B**, transfer to the new licensee
- OR
- Before the license is terminated, transfer records to the agency.

References: To obtain copies of RG 3.66 and P&GD FC 90-2 (Rev. 1), "*Standard Review Plan for Evaluating Compliance with Decommissioning Requirements*", dated April 30, 1991 are available at NRC's web site, <http://www.nrc.gov>.

Item 8: Facilities and Equipment

Rule: 12VAC5-481-450, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-840, 12VAC5-481-850, 12VAC5-481-860, 12VAC5-481-880

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

Discussion: Self-shielded irradiators incorporate many engineering features to protect individuals from unnecessary radiation exposure. These devices are usually designed for use in a laboratory environment (i.e., inside a building protected from the weather and without wide variations of temperature and humidity). For information to help applicants determine the location of irradiators, see the sections on the SSDR Certificate entitled, "*Conditions of Normal Use*" and "*Limitations and/or Other Considerations of Use*".

For example, if a proposed location for a self-shielded irradiator is not within the conditions of normal use or the limitations of use, the applicant will need to provide adequate justification. In addition, the applicant will need to take compensatory measures (e.g., increased surveillance and maintenance) to ensure that the irradiator operates as designed and provides the intended level of protection. NRC IN 96-35, "*Failure of Safety Systems on Self-Shielded Irradiators Because of Inadequate Maintenance and Training*", dated June 11, 1996, discusses an incident resulting from irradiator failure in which the lack of a climate-controlled environment (i.e., loading dock) may have accelerated the degradation of internal components leading to a failed interlock and excessive dose received by an irradiator operator.

Self-shielded irradiators vary in weight from several hundred to several thousand kilograms (pounds). Before installing an irradiator, licensees need to evaluate whether the floor in the proposed location can support the irradiator. Often licensees locate self-shielded irradiators on a ground floor. Some smaller and lighter irradiators require additional security measures to prevent unauthorized removal (e.g., locked in a room, bolted to the floor). For more information see **Item 9.6** 'Operating and Emergency Procedures' and **Item 9.5** 'Public Dose'.

The fire-resistant properties of most irradiators should provide adequate radioactive material containment and shielding integrity in most situations; however, additional protection is desirable for some situations. For example, the room housing the irradiator should be equipped with an automatically operated fire detection and control system (sprinkler, chemical, or gas). As an alternative, the self-shielded irradiator should be located under conditions (e.g., ground floor location in fire-resistant building with little combustible material) and other controls (e.g., coordination with and training of firefighting personnel) that ensure a low level of radiation risk attributable to fires.

The applicant should identify the self-shielded irradiator location by room number and should submit drawings of the location within the facility.

Provide the following on the facility diagrams:

- Drawings should be to scale, and indicate the scale used;
- Location, room numbers, and principal use of each room or area where radioactive material is used or stored;
- Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below; and,
- If multiple locations of storage, indicate address on diagram.

Response from Applicant:

<p>Item 8 Facilities And Equipment (Check all that apply)</p> <p><input type="checkbox"/> Diagrams of radioactive material area(s) of use are attached.</p> <p style="text-align: center;">AND EITHER</p> <p><input type="checkbox"/> We will ensure that each area where a self-shielded irradiator is located corresponds to the "<i>Conditions of Normal Use</i>" and "<i>Limitations and/or Other Considerations of Use</i>" on the applicable irradiator's Sealed Source and Device Registration Certificate; the floor beneath the self-shielded irradiator is secured to prevent unauthorized access or removal; and each area where a self shielded irradiator is located is equipped with an automatically operated fire detection and control system (sprinkler, chemical, or gas) or the location of the area and other controls ensure a low-level radiation risk attributable to fires.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will submit alternative information; be sure to include justification for placing an irradiator in an area that does not correspond to the "<i>Conditions of Normal Use</i>" and the "<i>Limitations and/or Other Considerations of Use</i>".</p>
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References: NRC INs are available at NRC's web site, <http://www.nrc.gov>.

Item 9: Radiation Safety Program

Item 9.1: Audit Program

Rule: 12VAC5-481-450, 12VAC5-481-500, 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 as low as is reasonably achievable (ALARA) (12VAC5-481-630); and
- Records of audits and other reviews of program content are maintained for 3 years.

Discussion: Appendix J contains a suggested audit program that is specific to the use of self-shielded irradiators and is acceptable to the agency. All areas indicated in Appendix J may not be applicable to every licensee and may not need to be addressed during each audit. For example, licensees do not need to address areas that do not apply to their activities or activities which have not occurred since the last audit. Generally, audits are conducted at least once every 12 months.

The agency's emphasis in inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of irradiator users to determine if, for example, operating and emergency procedures are available and are being followed.

It is essential that once identified, problems be corrected comprehensively and in a timely manner; NRC IN 96-28, *"Suggested Guidance Relating to Development and Implementation of Corrective Action"*, dated May 1, 1996, 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 comprehensive correction of violations and deficiencies.

Licensees must maintain records of audits and other reviews of program content and implementation for 3 years from the date of the record. The agency will find that audit records containing the following information to be acceptable: date of audit, name of person(s) who conducted audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up.

Response from Applicant:

Item 9.1 Audit Program

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

References: The documents referenced above are available electronically at NRC's web site, <http://www.nrc.gov>.

Item 9.2: Radiation Monitoring Instruments

Rule: 12VAC5-481-450 A, 12VAC5-481-490 B, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-740, 12VAC5-481-750, 12VAC5-481-1000

Criteria: Licensees must possess, or have access to, radiation monitoring instruments that are necessary to protect health and minimize danger to life or property. Instruments used for quantitative radiation measurements must be calibrated at intervals not to exceed 12 months for the radiation measured.

Discussion: All licensees possessing self-shielded irradiators should have, or have access to, calibrated radiation detection instruments to determine radiation levels in areas adjacent to the irradiator. Usually, it is not necessary for a licensee to have a survey meter solely for use during irradiator operations, since it is not expected that a survey be performed each time a sample is irradiated. In these cases it is acceptable for the meter to be available on short notice in the event of an accident or malfunction that could reduce the shielding of the sealed source(s). Surveys may be required to verify source integrity and to ensure that dose rates in unrestricted areas and public and occupational doses are within regulatory limits.

As explained in an "*Urgent Notice*" with an enclosed Order, both dated July 3, 1984 (see **Appendix E**), an NRC licensee identified a malfunction that could have resulted in a radiation overexposure. The malfunction involved an interlock mechanism that would have failed to prevent a shielded door from being opened after the source had moved out of the shielded position. The Order, which remains in effect, modifies licenses which authorize J. L. Shepherd Mark I or Model 81-22 irradiators and requires licensee to provide either a calibrated and operable radiation survey meter or room monitor for use with either of these irradiators. Although not required for all licensees possessing moving-source irradiators, it would be prudent for these licensees to use either a calibrated survey meter or room monitor to ensure that the sources are in the shielded position whenever a sample is not undergoing irradiation.

The agency requires that survey meter calibrations be performed by the instrument manufacturer or a person specifically authorized by VDH, the NRC or another Agreement State, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey meter calibrations must follow the survey instrument calibration program in **Appendix K** or submit alternative procedures for review.

Response from Applicant:

<p>Item 9.2 Radiation Monitoring Instruments (Check one box)</p> <p><input type="checkbox"/> We will use instruments that meet the radiation monitoring instrument specifications published in Appendix K of VAREG 'Guidance for Self-Shielded Irradiators'. Additionally, each survey meter will have been calibrated by the manufacturer or other person authorized by VDH, the NRC or another Agreement State to perform survey meter calibrations no more than 12 months before the date the meter is used.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will use instruments that meet the radiation monitoring instrument specifications published in Appendix K of VAREG 'Guidance for Self-Shielded Irradiators'. Additionally, we will implement the model survey meter calibration program published in Appendix K of VAREG 'Guidance for Self-Shielded Irradiators' and we ensure that each survey meter will have been calibrated no more than 12 months before the date the meter is used.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will have access to survey equipment and/or procedures for ensuring that interlocks function, as required, to return moving self-shielded irradiator sources to the shielded position and/or determining source shielding integrity after an incident involving the self-shielded irradiator.</p>

Notes:

- Licenses authorizing J. L. Shepherd Mark I or Model 81-22 irradiators will be conditioned to require compliance with the terms of the Order in **Appendix E**. Applicants requesting these irradiators must ensure that their radiation detection instruments meet these requirements.
- Applicants who plan to perform non-routine maintenance that will affect safety-critical components (e.g., sealed source, radiation shielding, source movement control or mechanism, interlocks) will need to possess and use appropriate, calibrated radiation survey meters. Refer to the section on **Item 9.8 Maintenance, Appendix I, and Appendix K** for more information.
- Required calibration records must be retained for a minimum of 3 years.

Item 9.3: Material Receipt and Accountability

Rule: 12VAC5-481-100, 12VAC5-481-450 C, 12VAC5-481-490 B, 12VAC5-481-500, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-740, 12VAC5-481-840, 12VAC5-481-900, 12VAC5-481-980, 12VAC5-481-1090, 12VAC5-481-3091, 12VAC5-481-3100

Criteria: Licensees must do the following:

- Maintain accountability for self-shielded irradiators by conducting physical inventories at intervals not to exceed 6 months (or as justified by the applicant) to account for all sealed sources.
- Maintain records of receipt, transfer, and disposal of self-shielded irradiators.

Discussion: While loss, theft, or misplacement of most self-shielded irradiators is unlikely because of their size and weight, accountability for licensed materials must be ensured. Many licensees record use of self-shielded irradiators in a logbook. Licensees are also required to conduct leak tests of irradiator sealed source(s) at the frequency specified in the SDR Certificate. Since both of these activities require that an individual approach the irradiator, records of use and leak tests may be used as part of an accountability program. For more information, see **Item 9.6** 'Operating and Emergency Procedures' and **Item 9.7** 'Leak Tests' in this guide. However, since some irradiators may not be in use or are used rarely, the agency expects licensees to physically approach and account for all sealed sources at least every 6 months.

'Cradle to Grave' accountability refers to maintaining the radioactive material from the moment it becomes a part of your organization 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).

Receipt, transfer, and disposal records must be maintained for the times specified in **Table 4**. Typically, these records contain the following types of information:

- Radionuclide and activity (in units of becquerels or curies) of radioactive material in each sealed source
- Manufacturer's (or distributor's) name, model number, and serial number (if appropriate) of each device containing radioactive material
- Location of each sealed source and device
- For materials transferred or disposed of, the date of the transfer or disposal, name and license number of the recipient, description of the affected radioactive material (e.g., radionuclide, activity, manufacturer's (or distributor's) name and model number, serial number).

Information on locations where irradiators are used or stored are records important to decommissioning and required by **12VAC5-481-450 C**.

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

* See the Item 7.1 'Financial Assurance and Recordkeeping for Decommissioning'.

Response from Applicant:

<p>Item 9.3 Material Receipt And Accountability (Check box)</p> <p><input type="checkbox"/> Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license.</p>
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Item 9.4: Occupational Dose

Rule: 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-700, 12VAC5-481-710, 12VAC5-481-750, 12VAC5-481-760, 12VAC5-481-770, 12VAC5-481-1040, 12VAC5-481-1130, 12VAC5-481-1140, 12VAC5-481-2280

Criteria: Applicants must do either of the following:

- Perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits as shown in **Table 5**.

OR

- Provide dosimetry as follows:
 - Personnel dosimeters which are processed and evaluated by a National Voluntary Laboratory Accreditation Program (NVLAP) approved processor and are exchanged at a frequency recommended by the processor; or
 - Direct or indirect reading pocket ionization chambers that:
 - Are assigned to a single individual whose accumulated dose is read, recorded, and the chamber recharged, as appropriate, before the chamber is assigned to another individual
 - Have a range of 0 to at least 2 mSv (200 mrem)
 - Are checked at intervals not to exceed one year for correct response to radiation
 - Read within $\pm 20\%$ of the true radiation exposure
 - Are used under a program that prescribes action to evaluate the individual's dose

Table 5. Occupational Dose Limits for Adults

Occupational Dose Limits for Adults (12VAC5-481-640)	
<u>Body Location</u>	<u>Dose (Annual)</u>
Total Effective Dose Equivalent (Dose to Whole Body)	0.05 Sv (5 Rem)
Dose to the skin and extremities*	0.5 Sv (50 Rem)
Dose to lens of the eyes	0.15 Sv (15 Rem)
*Extremities includes the arms below the elbows and the legs below the knees	

Discussion: Under conditions of routine use and maintenance, the typical self-shielded irradiator user does not require a personnel monitoring device (dosimetry). However, individuals who perform non-routine maintenance do require personnel monitoring devices. **Appendix L** provides guidance on performing a prospective evaluation demonstrating that self-shielded irradiator users are not likely to exceed 10% of the applicable limits and thus, are not required to have personnel dosimetry.

When personnel monitoring is needed, most licensees use either film badges, OSLs or other approved similar devices that are supplied by a NVLAP-approved processor. The exchange frequency for film badges is usually monthly due to technical concerns about film fading. The exchange frequency for OSLs is usually quarterly. Applicants should verify that the processor is NVLAP-approved. Consult with the NVLAP-approved processor for its recommendations for exchange frequency and proper use.

Some licensees use self-reading dosimeters in lieu of processed dosimetry. This is acceptable if the criteria above are met. See ANSI N322, "*Inspection and Test Specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters*", for more information.

Response from Applicant:

<p>Item 9.4 Occupational Dose (Check one box)</p> <p><input type="checkbox"/> 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.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged at a frequency recommended by the processor.</p>

Note: Some licensees choose to provide personnel dosimetry to their workers for reasons other than compliance with VDH requirements (e.g., to respond 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.

Item 9.5: Public Dose

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

Criteria: Licensees must do the following:

- Ensure that licensed self-shielded irradiators will be used, transported, and stored in such a way that members of the public will not receive more than 1 mSv (100 mrem) in one year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour, from licensed operations.
- Control and maintain constant surveillance over self-shielded irradiators that are not in storage and secure stored self-shielded irradiators from unauthorized access, removal, or use.

Discussion: Public dose is defined in 12VAC5-481-10 as *“the dose received by a member of the public from exposure to sources of radiation released by a licensee or registrant, or to any other source of radiation under the control of a licensee or registrant.”* Public dose excludes doses received from background radiation and from medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individual's assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) the individual is in when the dose is received.

In the case of self-shielded irradiators, members of the public include persons who work or may be near locations where self-shielded irradiators are used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where irradiators are used or stored.

Irradiators should be located away from occupied areas and secured to prevent unauthorized use or removal. Security procedures described in **Item 8** ‘Facilities and Equipment’ and **Item 9.6** ‘Operating and Emergency Procedures’ should be effective in limiting the exposure to the public during use or storage. Public dose is controlled, in part, by ensuring that irradiators are secure (e.g., located in a locked area) to prevent unauthorized access or use. Most self-shielded irradiators are massive [i.e., hundreds of kilograms (pounds) and the size of file cabinets], thus not likely to be easily removed from their intended location.

Smaller units, however, such as those used to calibrate TLDs, are more easily moved and should be located in a locked area or bolted in place. Irradiator use is usually restricted by controlling access to the keys needed to operate the irradiator and/or to keys to the locked irradiator area. Only authorized users should have access to these keys.

Public dose is also affected by the choice of storage and use locations and conditions. Since a self-shielded irradiator presents a radiation field, it must be located so that the radiation level in an unrestricted area (e.g., an office or the exterior surface of an outside wall) does not exceed 1 mSv (100 mrem) in a year or 0.02 mSv (2 mrem) in any one hour. Use the concepts of time, distance, and shielding when choosing storage and use locations. Decreasing the time spent near an irradiator, increasing the distance from the irradiator, and using shielding (i.e., brick, concrete, lead, or other solid walls) will reduce the radiation exposure.

Licensees can determine the radiation levels adjacent to the irradiator location either by calculations or a combination of direct measurements and calculations using some or all of the following: typical known radiation levels provided by the irradiator manufacturer (or distributor), the inverse square law to evaluate the effect of distance on radiation levels,

occupancy factor to account for the actual presence of the member of the public, and limits on the use of self-shielded irradiator(s). See **Appendix M** for an example.

If, after making an initial evaluation, a licensee changes the conditions used for the evaluation (e.g., changes the location of irradiators, changes the type or frequency of irradiator use, adds self-shielded irradiators, changes the occupancy of adjacent areas), then the licensee must perform a new evaluation to ensure that the public dose limits are not exceeded and take corrective action, as needed.

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

Response from Applicant:

Item 9.5 Public Dose

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

Item 9.6: Operating and Emergency Procedures

Rule: 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-630, 12VAC5-481-740, 12VAC5-481-750, 12VAC5-481-840, 12VAC5-481-860, 12VAC5-481-880, 12VAC5-481-900, 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1150, 12VAC5-481-2260

Criteria: Before using an irradiator, licensees must do the following:

- Develop, implement, and maintain model-specific operating and emergency procedures containing the following elements:
 - An analysis of each type of material to be placed in the irradiator to ensure that it is compatible with the irradiator's design or to determine if any special safety procedures are needed
 - Instructions for using the self-shielded irradiator and performing routine maintenance, according to the manufacturer's (or distributor's) written recommendations and instructions
 - Instructions for maintaining security to prevent unauthorized use, access, or removal of self-shielded irradiators and the associated sealed sources
 - Steps to take to keep radiation exposures ALARA
 - Steps to maintain accountability
 - Steps to control access to malfunctioning or damaged irradiator
 - Steps to take, and whom to contact (e.g., RSO, local officials), when an irradiator malfunctions or has been damaged.
- AND
- Provide copies of operating and emergency procedures to all users.
 - Maintain a current copy of operating and emergency procedures at each irradiator's control panel (or, if this is not practicable, post a notice describing the procedures and stating where they may be examined).

Discussion: When used as designed, properly functioning self-shielded irradiators pose little radiation safety risk. However, improper maintenance, irradiating material incompatible with an irradiator's design, or operating an irradiator in an environment other than that

recommended by the manufacturer (or distributor), could lead to damage or malfunction of an irradiator and elevated exposure rates in the irradiator's immediate vicinity. Operating and emergency procedures should be developed to minimize these risks, while keeping radiation exposures ALARA. These procedures must be model-specific to account for potentially significant differences in irradiator design and construction that lead to manufacturers (or distributors) providing different instructions and recommendations for operating and maintaining irradiators.

Sources contained in many self-shielded irradiators are designed to deliver significant doses in short periods of time. Although self-shielded irradiators are safe when used correctly, unauthorized access to the irradiator or the irradiator's sources by untrained individuals could lead to a life-threatening situation. Therefore, operating procedures will also need to address access control and accountability. Many licensees achieve access control by permitting only AUs or the RSO to have access to the keys for the irradiator and/or the irradiator area. Accountability of an operating irradiator may be ensured by using a logbook to record irradiator use, maintenance, service calls, and sealed source leak tests. Each activity requires an individual to interact in some way with the irradiator and thereby verify its presence. For sources contained in irradiators that are not actively used, licensees would need to find other methods to maintain accountability, such as conducting inventories.

Licensees must post current copies of the operating procedures applicable to licensed activities (e.g., at the irradiator control panel). If posting of a document is not practicable, the licensee may post a notice which describes the document and states where it may be examined.

Emergency procedures should be developed to address a spectrum of incidents (e.g., interlock failure, flood, earthquake). Emergency response procedures should contain the following:

- Leave the irradiator room to reduce radiation exposure
- Control access (e.g., lock door)
- Contact the individual responsible for the irradiator program for further instructions and to initiate emergency response actions. Telephone numbers should be posted or easily accessible and should include the responsible individual, the irradiator manufacturer, distributor, or its representative, fire department, emergency response organizations, and the agency

VDH Emergency Response Telephone Numbers:
(804) 864-8150 during office hours and
(804) 674-2400 or (800) 468-8892 for 24-hr emergency response

- Survey areas outside the irradiator room to determine whether further restriction of the area is necessary to ensure that no one can enter the area if the radiation level exceeds 0.02 mSv (2 mrem) per hour
- As appropriate, require timely reporting to the agency according to **12VAC5-481-1090**, **12VAC5-481-1100**, **12VAC5-481-1110**, and **12VAC5-481-1150**.

The agency must be notified when a self-shielded irradiator is lost, stolen, or other conditions occur. The RSO must be proactive in evaluating whether agency notification is required. Refer to **Appendix N** and the regulations (**12VAC5-481-1090**, **12VAC5-481-1100**, **12VAC5-481-1110**, and **12VAC5-481-1150**) for a description of when and where notifications are required.

Appendix O provides information for applicants to consider when developing their procedures for self-shielded irradiators.

Response from Applicant:

Item 9.6 Operating And Emergency Procedures (Check one box)

- We will develop, implement, maintain and distribute operating procedures that will meet the Criteria in the section titled 'Operating and Emergency Procedures' in VAREG 'Guidance for Self-shielded Irradiators'. (Procedures are attached)

OR

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

Note:

- Licenses authorizing J. L. Shepherd Mark I or Model 81-22 irradiators will be conditioned to require compliance with the terms of the Order in **Appendix E**. Applicants requesting these irradiators must ensure that their operating and emergency procedures address these requirements.
- Before using a new model irradiator, licensees need to revise operating and emergency procedures to include procedures specific to the new irradiator.

Item 9.7: Leak Tests

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

Criteria: The agency requires testing to determine whether there is any radioactive leakage from the source in the self-shielded irradiator. Records of test results must be maintained for five years.

Discussion: Licensees will perform leak tests at six-month intervals or as approved in the SSDR Certificate. The measurement of the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the sample is capable of detecting 185 Bq (0.005 microcurie) of radioactivity.

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

Response from Applicant:

Item 9.7 Leak Tests (Check one box)

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

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

Organization Name _____ License Number _____
Issuing Agency _____

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

OR

- We will perform leak testing and sample analysis and will follow the model procedures in Appendix P of VAREG 'Guidance for Self-Shielded Irradiators'. (Procedures are attached)

OR

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

Note:

- Alternative responses will be reviewed using the criteria listed above.
- If a self-shielded irradiator is added to an existing license, that license might already authorize the licensee to perform the entire leak test sequence. In this case, the licensee may perform the leak testing on the irradiator according to the procedures previously approved on its license.

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

Item 9.8: Maintenance

Rule: 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-980

Criteria: Licensees must routinely maintain self-shielded irradiators according to the manufacturer's (or distributor's) written recommendations and instructions. For self-shielded irradiators, radiation safety procedures for routine maintenance must consider ALARA and ensure that the irradiator functions as designed and source integrity is not compromised.

In this guide, 'non-routine maintenance' means any repair, removal, replacement, or alteration involving: electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, any component that may affect safe operation of the irradiator, or any other activities during which personnel could receive radiation doses exceeding VDH limits.

Non-routine maintenance must be performed by the self-shielded irradiator manufacturer (or distributor) or a person specifically authorized by VDH, the NRC or another Agreement State. Requests for specific authorization to perform non-routine maintenance (see **Appendix I**) must demonstrate that personnel performing the work do the following:

- Have adequate training and experience
- Use equipment and procedures that ensure compliance with regulatory requirements, and consider ALARA
- Ensure that the self-shielded irradiator functions as designed and that source integrity is not compromised.

Discussion: NRC IN 96-35, "Failure of Safety Systems on Self-Shielded Irradiators because of Inadequate Maintenance and Training", dated June 11, 1996, emphasizes the importance of proper maintenance and describes two incidents in which safety interlocks on self-shielded irradiators failed to prevent inadvertent exposure. Generally, before any maintenance or repair work is done, licensees need to determine (and assure themselves of the adequacy of) the following:

- The tasks to be performed
- The protocol or procedures to be followed
- The radiation safety procedures including possible need for compensatory measures (e.g., steps taken to compensate for lack of or reduced shielding)
- ALARA considerations
- Training and experience of personnel performing the work
- The qualification of parts, components, other materials to be used in the irradiator
- The tests (to be performed before the irradiator is returned to routine use) to ensure that it functions as designed.

VDH permits self-shielded irradiator licensees to perform routine maintenance of the irradiator provided they follow the self-shielded irradiator manufacturer's (or distributor's) written recommendations and instructions. Although manufacturers (or distributors) may use different terms, 'routine maintenance' includes, but is not limited to, cleaning, lubrication, changing batteries, relays or fuses. Routine maintenance does **not** include any activities that involve the source, source drive mechanism, or removing the shielding or source and any other activities during which personnel could receive radiation doses exceeding VDH limits.

The VDH license will require that non-routine maintenance (as defined above) be performed only by the manufacturer (or distributor) or other persons specifically licensed by VDH, the NRC or another Agreement State to perform such services. Most licensees do not perform non-routine maintenance because they must have specialized equipment and technical expertise to perform these activities. Applicants seeking authorization to perform non-routine maintenance must submit specific procedures for review. See **Appendix I** for more information.

Response from Applicant:

<p>Item 9.8 Maintenance (Check one box for Routine Cleaning and Lubrication and one for Non-Routine Maintenance)</p> <p>ROUTINE CLEANING AND LUBRICATION:</p> <p><input type="checkbox"/> We will implement and maintain procedures for routine maintenance of our self-shielded irradiators according to each manufacturer's (or distributor's) written recommendations and instructions.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> Alternative procedures are attached.</p> <p>NON-ROUTINE MAINTENANCE:</p> <p><input type="checkbox"/> We will have the self-shielded irradiator manufacturer (or distributor) or other person authorized by VDH, the NRC or another Agreement State perform the non-routine maintenance.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will provide procedures that address the information listed in Appendix I of VAREG 'Guidance for Self-Shielded Irradiators' supporting a request for authorization to perform this work. (Procedures are attached)</p>

Note: Information requested in **Appendix I** will be reviewed on a case-by-case basis; if approved, the license will contain a condition authorizing the licensee to perform non-routine maintenance.

References: NRC INs are available electronically at NRC's web site, <http://www.nrc.gov>.

Item 9.9: Transportation

Rule: 12VAC5-481-100, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-2980, 12VAC5-481-3000, 12VAC5-481-3010, 12VAC5-481-3020, 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 must develop, implement, and maintain safety programs for transport of radioactive material to ensure compliance with VDH and DOT regulations.

Discussion: Most irradiator licensees chose to transfer possession of radioactive materials to an irradiator manufacturer, distributor, or service licensee licensed with VDH, the NRC or another Agreement State who then acts as the shipper. The manufacturer, distributor, or service licensee is subject to the provisions of **12VAC5-481-3000** or **12VAC5-481-3010**, as appropriate. They are responsible for proper packaging of the radioactive materials and compliance with VDH and DOT regulations. Licensees who do this must ensure that the manufacturer, distributor, or service licensee:

- Is authorized to possess the irradiator at temporary job sites (e.g., at the irradiator location)
- Actually takes possession of the irradiator under its license
- Uses an approved Type B package
- Is registered with NRC as a user of the Type B package
- Has a VDH, NRC or another Agreement State approved QA plan.

For each shipment, it must be clear who possesses the licensed material and is responsible for proper packaging of the radioactive materials and compliance with VDH and DOT regulations.

The general license in **12VAC5-481-2980** provides the authorization used by most licensees to transport, or offer for transport, packages of radioactive material and specifies certain conditions. Most self-shielded irradiators contain quantities of radioactive material that require using a Type B package. Before offering a Type B package for shipment, the licensee needs to be registered as a user of the package and have an NRC-approved quality assurance (QA) plan, two of the requirements under the **12VAC5-481-3000** general license. For information about QA plans, see Rev. 1 of NRC RG 7.10, "*Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material*," dated June 1986. For further information about registering as a user of a package, contact NRC's Spent Fuel Project Office (SFPO) by calling NRC's toll-free number 800-368-5642 and asking for extension 415-8500. For information about associated fees, contact NRC's OCFO by calling NRC's toll-free number 800-368-5642 and asking for extension 415-7554.

During an inspection, the agency uses the provisions of **12VAC5-481-2980** to examine and enforce various DOT requirements applicable to irradiator licensees. **Part 1 of Appendix Q** lists major DOT regulations and **Part 2** contains a sample bill of lading.

Before the adoption of the requirements of **10 CFR Part 71** in 1966, self-shielded irradiators could be transported without being evaluated under the hypothetical accident conditions that are now incorporated in **10 CFR 71**. Because pre-1966 irradiators are not certified shipping packages, transporting them may require transferring the sealed source from the irradiator to a certified Type B package or using a certified package for the irradiator containing the sealed sources. Only if these options are not viable will VDH consider a licensee's request for an exemption for a one-time shipment from **12VAC5-481-3130**. Exemption requests should contain the information described in Part 3 of **Appendix Q**. In addition to a VDH exemption, the licensee may also need a DOT exemption; contact DOT's Office of Hazardous Materials Technology at 202-366-4545 for additional information.

Response from Applicant:

Item 9.9 Transportation

We choose to transfer possession of radioactive material to an irradiator manufacturer, distributor, or service licensee with a VDH, NRC or another Agreement State license who then acts as the shipper.

OR

Before offering a Type B package for shipment we will be registered with the NRC as user of the package and obtain VDH approval of our QA program.

References: "A Review of Department of Transportation Regulations for Transportation of Radioactive Materials (1998 revision)" can be obtained by calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4425 or at the following website, <http://hazmat.dot.gov/>. NRC Regulatory Guides are available electronically at NRC's web site, <http://www.nrc.gov>.

Item 9.10: Minimization of Contamination

Rule: 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-630, 12VAC5-481-740, 12VAC5-481-1150, 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. Irradiator applicants usually do not need to address these issues as a separate item since they are included in responses to other items of the application.

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

Note: The agency will consider that the above criteria has been met if the applicant's responses meet the criteria in the following items: **Item 7** 'Radioactive Material'; **Item 9.6** 'Operating and Emergency Procedures'; **Item 9.7** 'Leak Test'; **Item 10** 'Disposal, Transfer and License Termination'.

Item 10: Disposal, Transfer and License Termination

Item 10.1: Disposal and Transfer

Rule: 12VAC5-481-100, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-910, 12VAC5-481-980, 12VAC5-481-2980, 12VAC5-481-3100

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

Discussion: When disposing of self-shielded irradiators, licensees must transfer them to an authorized recipient. Authorized recipients are the original manufacturer (or distributor) of the irradiator, a commercial firm licensed by VDH, the NRC or another Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material (i.e., its license specifically authorizes the same radionuclide, form, and use).

Before transferring radioactive material, a licensee must verify that the recipient is properly authorized to receive it using one of the methods described in 12VAC5-481-570. In addition, all packages containing radioactive sources must be prepared and shipped according to VDH and DOT regulations. Records of the transfer must be maintained as required by 12VAC5-481-100 and 12VAC5-481-571.

Licensees should promptly dispose of unused irradiators to minimize potential problems of access by unauthorized individuals, use for inappropriate purposes, or improper disposal.

Response from Applicant:

Item 10.1 Disposal And Transfer (Check Box)

- We will return the source to the manufacturer for disposal or transfer the device to a specific licensee authorized to receive radioactive material.

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

Item 10.2: Termination of Activities

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-1161

Criteria: The licensee must do the following:

- Notify the agency, in writing, within 60 days of:
 - The expiration of its license
 - A decision to permanently cease licensed activities at the entire site (regardless of contamination levels)
 - A decision to permanently cease licensed activities in any separate building or outdoor area, if they contain residual radioactivity making them unsuitable for release according to VDH requirements

- No principal activities having been conducted at the entire site under the license for a period of 24 months
- No principal activities having been conducted for a period of 24 months in any separate building or outdoor area, if they contain residual radioactivity making them unsuitable for release according to VDH requirements.
- Submit a decommissioning plan, if required by **12VAC5-481-510**.
- Conduct decommissioning, as required by **12VAC5-481-510** and **12VAC5-481-1161**.
- Submit, to the agency, a completed VDH Form, 'Certificate of Disposition of Materials' (or equivalent information) and a demonstration that the premises are suitable for release for unrestricted use (e.g., results of final survey).
- Before a license is terminated, send the records important to decommissioning to the agency. If licensed activities are transferred or assigned in accordance with **12VAC5-481-500 B**, transfer records important to decommissioning to the new licensee.

Discussion: As noted in several instances discussed in 'Criteria', before a licensee can decide whether it must notify the agency, the licensee must determine whether residual radioactivity is present and if so, whether the levels make the building or outdoor area unsuitable for release according to VDH requirements. A licensee's determination that a facility is not contaminated is subject to verification by agency inspection.

For guidance on the disposition of licensed material, see the **Item 10**, 'Disposal, Transfer and License Termination'. For guidance on decommissioning records, see **Item 7.1** 'Financial Assurance and Record Keeping for Decommissioning'.

Response from Applicant:

<p>Item 10.2 Termination Of Activities (Check box)</p> <p><input type="checkbox"/> We will notify the agency, in writing, within 60 days of the decision to permanently cease radioactive material use per 12VAC5-481-500.</p>
--

Reference: See **Appendix B** for VDH Form, 'Certificate of Disposition of Materials.'

Item 11: License Fees

Rule: 12VAC5-491

Criteria: On VDH Form, 'Application for Radioactive Material Authorizing the Use of Self-Shielded Irradiator Devices' (**Appendix A**), enter the fee category and the amount. Refer to **12VAC5-481-490** for fee category and application fees. Enclose fee with the application.

Response from Applicant:

<p>Item 11 License Fees (Refer to 12VAC5-490.)</p>	
<p>Category: _____</p>	<p>Application fee enclosed (for new applications): <input type="checkbox"/> Yes <input type="checkbox"/> No Amount Enclosed _____</p>

Item 12: Certification

Criteria:

- Individuals acting in a private capacity are required to sign and date VDH Form, 'Application for Radioactive Material License Authorizing the Use of Self-Shielded Irradiators' (**Appendix A**).
- Senior representatives of the corporation or legal entity filing the application should sign and date VDH Form, 'Application for Radioactive Material License Authorizing the Use of Self-Shielded Irradiators' (**Appendix A**).

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

Response from Applicant:

Item 12	
I hereby certify that this application was prepared in conformance with 12VAC5-481 'Virginia Radiation Protection Regulations' and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.	
SIGNATURE - Applicant Or Authorized Individual	Date signed:
Print Name and Title of above signatory	

Note:

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

Appendix A

VDH Form

‘Application for Radioactive Material License Authorizing the Use of Self-Shielded Irradiators’

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



**APPLICATION FOR RADIOACTIVE MATERIAL LICENSE
 AUTHORIZING THE USE OF SELF-SHIELDED IRRADIATORS**

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

Instructions – Complete all items if this is an initial application or an application for renewal of a license. Refer to VAREG “Guidance for Self-Shielded Irradiators.” Use supplementary sheets where necessary. Retain one copy and submit original of the entire application to: Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219.

APPLICATION TYPE

Item 1 Type Of Application (Check one box)

New License Renewal License Number _____

CONTACT INFORMATION

Item 2 Name And Mailing Address Of Applicant:

Item 3 Person To Contact Regarding Application:

Applicant’s Telephone Number (Include area code):

Contact’s Telephone Number (Include area code):

LOCATION OF RADIOACTIVE MATERIAL

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

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

RADIATION SAFETY OFFICER

Item 5. Radiation Safety Officer (RSO) (Check one box and attach evidence of training and experience)

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

Before obtaining radioactive material, the proposed RSO will have successfully completed training as described in Appendix G of VAREG ‘Guidance For Self-Shielded Irradiators’. Before being named as the RSO, future RSOs will have successfully completed training as described in Appendix G of VAREG ‘Guidance For Self-Shielded Irradiators’

OR

Alternative information demonstrating that the proposed RSO is qualified by training and experience is attached. Before being named as the RSO, future RSOs will have successfully completed training as described in Appendix G of VAREG ‘Guidance For Self-Shielded Irradiators’.

AUTHORIZED USERS

Item 6 Authorized Users (Check one box)

Before using radioactive material, authorized users will have received training as described in Appendix G in VAREG 'Guidance for Self-Shielded Irradiators.'

OR

A description of the training and experience for proposed authorized users is attached.

RADIOACTIVE MATERIAL

Item 7 Radioactive Material (Attach additional pages if necessary)

ELEMENT AND MASS NUMBER

Cobalt-60 Cesium-137 Strontium-90 Other Isotope (please specify):

SEALED SOURCE MANUFACTURER OR DISTRIBUTOR AND MODEL NUMBER:

DEVICE MANUFACTURER OR DISTRIBUTOR AND MODEL NUMBER:

MAXIMUM QUANTITY (Not to exceed either the maximum activity per source or device as specified in the Sealed Source and Device Registration Certificate)

INTENDED USE

FACILITIES AND EQUIPMENT

Item 8 Facilities And Equipment (Check all that apply)

Diagrams of radioactive material area(s) of use are attached.

AND EITHER

We will ensure that each area where a self-shielded irradiator is located corresponds to the 'Conditions of Normal Use' and 'Limitations and/or Other Considerations of Use' on the applicable irradiator's Sealed Source and Device Registration Certificate; the floor beneath the self-shielded irradiator is secured to prevent unauthorized access or removal; and each area where a self-shielded irradiator is located is equipped with an automatically operated fire detection and control system (sprinkler, chemical, or gas) or the location of the area and other controls ensure a low-level radiation risk attributable to fires.

OR

We will submit alternative information; be sure to include justification for placing an irradiator in an area that does not correspond to the 'Conditions of Normal Use' and the 'Limitations and/or Other Considerations of Use.'

RADIATION SAFETY PROGRAM

Item 9 Radiation Safety Program

Item 9.1 Audit Program

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

Item 9.2 Radiation Monitoring Instruments (Check one box)

We will use instruments that meet the radiation monitoring instrument specifications published in Appendix K of VAREG 'Guidance for Self-Shielded Irradiators'. Additionally, each survey meter will have been calibrated by the manufacturer or other person authorized by VDH, the NRC or another Agreement State to perform survey meter calibrations no more than 12 months before the date the meter is used.

OR

We will use instruments that meet the radiation monitoring instrument specifications published in Appendix K of VAREG 'Guidance for Self-Shielded Irradiators'. Additionally, we will implement the model survey meter calibration program published in Appendix K of VAREG 'Guidance for Self-Shielded Irradiators' and we ensure that each survey meter will have been calibrated no more than 12 months before the date the meter is used.

OR

We will have access to survey equipment and/or procedures for ensuring that interlocks function, as required, to return moving self-shielded irradiator sources to the shielded position and/or determining source shielding integrity after an incident involving the self-shielded irradiator.

Item 9.3 Material Receipt And Accountability (Check box)

Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license.

Item 9.4 Occupational Dose (Check one box)

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

OR

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

Item 9.5 Public Dose

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

Item 9.6 Operating And Emergency Procedures (Check one box)

We will develop, implement, maintain and distribute operating procedures that will meet the Criteria in the section titled 'Operating and Emergency Procedures' in VAREG 'Guidance for Self-Shielded Irradiators'. (Procedures are attached)

OR

We will submit alternative procedures. (Procedures are attached)

Item 9.7 Leak Tests (Check one box)

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

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

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

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

OR

We will perform leak testing and sample analysis and will follow the model procedures in Appendix P of VAREG 'Guidance for Self-Shielded Irradiators'. (Procedures are attached)

OR

We will submit alternative procedures. (Procedures are attached)

Item 9.8 Maintenance (Check one box for Routine Cleaning and Lubrication and one for Non-Routine Maintenance)

ROUTINE CLEANING AND LUBRICATION:

[] We will implement and maintain procedures for routine maintenance of our self-shielded irradiators according to each manufacturer's (or distributor's) written recommendations and instructions.

OR

[] Alternative procedures are attached.

NON-ROUTINE MAINTENANCE:

[] We will have the self-shielded irradiator manufacturer (or distributor) or other person authorized by VDH, the NRC or another Agreement State perform the non-routine maintenance.

OR

[] We will provide procedures that address the information listed in Appendix I of VAREG 'Guidance for Self-Shielded Irradiators' supporting a request for authorization to perform this work. (Procedures attached)

Item 9.9 Transportation (Check one box)

[] We choose to transfer possession of radioactive material to an irradiator manufacturer, distributor or service licensee with a VDH, NRC or another Agreement State license who then acts as the shipper.

OR

[] Before offering a Type B package for shipment we will be registered with the NRC as user of the package and obtain VDH approval of our QA program.

DISPOSAL, TRANSFER AND LICENSE TERMINATION

Item 10 Disposal, Transfer and License Termination

Item 10.1 Disposal And Transfer (Check Box)

[] We will return the source to the manufacturer for disposal or transfer the device to a specific licensee authorized to receive radioactive material.

Item 10.2 Termination Of Activities (Check box)

[] We will notify the agency, in writing, within 30 days of the decision to permanently cease radioactive material use per 12VAC5-481-500.

SPECIFIC LICENSE FEE

Item 11 License Fees (Refer to 12 VAC 5-490.)

Category:

Application fee enclosed (for new applications):

[] Yes [] No Amount Enclosed:

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

Item 12

I hereby certify that this application was prepared in conformance with 12VAC5-481, 'Virginia Radiation Protection Regulations' and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.

SIGNATURE - Applicant Or Authorized Individual

Date signed:

Print Name and Title of above signatory

Appendix B

VDH Form

‘Certificate of Disposition of Materials’



CERTIFICATE OF DISPOSITION OF MATERIALS

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

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

CONTACT INFORMATION

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

TERMINATION AND DISPOSITION INFORMATION

The following information is provided in accordance with 12VAC5-481-510. (Check all that apply)

- Item 4** All use of radioactive material authorized under the above referenced license has been terminated.
- Item 5** Radioactive contamination has been removed to the levels outlined in 12VAC5-481-1161 B.
- Item 6** All radioactive material previously procured and/or possessed under the authorization granted by the above referenced license has been disposed of as follows. (Check all that apply)
 - Transferred to: Name Address

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

Issued by (Licensing Agency):

- Decayed, surveyed and disposed of as non-radioactive waste.
- No radioactive material has ever been procured and/or possessed by the licensee under the authorization granted by the above referenced license.
- Other (Attach additional pages)

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

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

Name:

Address:

Contact Person Telephone Number: () - X

Additional remarks (Attach additional pages if necessary.)

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

Item 10.

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

SIGNATURE - Applicant or Authorized Individual

Date signed

Print Name and Title of Above Signatroy

Appendix C

Sample Correspondence Delegation Letter

SAMPLE CORRESPONDENCE DELEGATION LETTER

[date]

[name and address]

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

To Director Radioactive Material Program:

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

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

Signature

Title

Date

Print Name

Appendix D

Information Needed for Transfer of Control Application

Information Needed for Transfer of Control

Licensees must provide full information and obtain the agency'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.

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

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

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

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

References: The information above is derived from NRC Information Notice 89-25, Revision 1, "*Unauthorized Transfer of Ownership or Control of Licensed Activities*", which is available at the NRC's webpage at <http://www.nrc.gov>.

Appendix E

J. L. Shepherd Order

J. L. Shepherd Order

JULY 3, 1984
UNITED STATES
NUCLEAR REGULATORY COMMISSION
URGENT NOTICE

TO ALL LICENSEES WHO POSSESS J. L. SHEPHERD IRRADIATORS

An NRC licensee recently identified a malfunction in the lock mechanism of its J. L. Shepherd self-shielded irradiator which could have resulted in a radiation overexposure. Although no overexposure appears to have occurred, the potential hazard warrants immediate preventive action. Therefore, we have prepared the enclosed Order which requires the use of radiation survey equipment when the irradiators are being used.

If you possess a J. L. Shepherd Mark I or Model 81-22 self-shielded irradiator, do not use it unless you provide appropriate radiation monitoring as specified in the Order. If you do not currently possess the appropriate equipment, you must obtain it before you resume use of your irradiator. Also, you should report any problems to your nearest NRC regional office immediately. Do not attempt to repair an irradiator, or allow anyone else to attempt repairs, unless specific authorization for repair of the irradiator which you possess is provided in an NRC license.

We suggest that you review who has access to your irradiator, and establish strict controls to assure that no untrained personnel have access. Trained persons who continue to use the irradiator should conduct careful radiation surveys as specified in the Order. Irradiator doors should be opened slowly, to minimize any accidental exposure and to avoid "blinking out" of instruments due to high exposure rates. Any unusual meter reading should be taken as evidence of a problem.

We are including in this mailing certain licensees about which we are uncertain whether they possess J. L. Shepherd irradiators. If you do not possess a J. L. Shepherd irradiator, please disregard this notice.

Because this Order is effective immediately, it is important that you notify your radiation safety personnel immediately, and retain this Order with your license records. Questions and comments may be directed to your nearest NRC regional office.

Sincerely,
Richard E. Cunningham, Director
Division of Fuel Cycle and Material Safety
Enclosure: Order Modifying License

**UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D. C. 20555**

ORDER MODIFYING CERTAIN LICENSES (EFFECTIVE IMMEDIATELY)

I

Recently, the Nuclear Regulatory Commission (NRC) staff was notified by a licensee of the failure of a locking mechanism on a self-shielded irradiator which could have resulted in a radiation overexposure. ("Self-shielded" irradiators are designed so that the radioactive source remains in a shielded position at all times, both during storage and during irradiations. Therefore, the irradiators need not be placed in a shielded room.)

The irradiator is a J. L. Shepherd Mark I, containing about 6,000 curies of cesium 137. The unit is operated as follows: (1) With the source in its shielded storage position, the shielded door is opened, (2) materials to be irradiated are placed inside the irradiator chamber, (3) the shielded door is closed, (4) the radioactive source is raised into the irradiation chamber, (5) after irradiation is complete, the source is lowered, and (6) the door is opened for removal of irradiated materials.

The shielded door is interlocked so that it should not open when the radioactive source is in the irradiation chamber. However, in the case reported to NRC, the lock mechanism failed. In such a situation, an operator who opens the shielded door with the source raised could be subjected to substantial radiation exposure. The J. L. Shepherd Model 81-22 irradiator employs an interlock similar to the Mark I.

The NRC staff has examined the irradiator in question and confirmed the defect. Furthermore, a New York City inspector checking a J. L. Shepherd Mark I irradiator in New York reported a malfunctioning interlock system. NRC and the Agreement States are studying the problem further to assess its generic implications.

Based on the foregoing, I have concluded that the possibility of failure of locking mechanisms and/or mechanical timers on J. L. Shepherd Mark I and Model 81-22 irradiators represents a potential radiation hazard warranting immediate preventive action pending further investigation. I have determined, therefore, that the public health, safety, and interest require that the restrictions on the use of such irradiators as prescribed in Section II of this Order should be made immediately effective.

II

Accordingly, pursuant to Sections 81, 116 I, 162 o, and 182 of the Atomic Energy Act of 1954, as amended, and 10 CFR Parts 2 and 30 of the Commission's regulations, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT:

Each license that authorizes possession of byproduct material in a J. L. Shepherd Mark I or Model 81-22 self-shielded irradiator is hereby amended to add the following conditions:

1. The J. L. Shepherd irradiator shall not be used unless the licensee provides a calibrated and operable radiation survey meter or room monitor for use with the irradiator.
2. The irradiator door shall not be opened until the operator has checked visual indicators to verify that the source has returned to its safe storage position.
3. Each room monitor (a) shall be operable at all times when the irradiator is in use, (b) shall activate a visible and audible alarm when radiation levels exceed 2 millirems per hour, (c) shall be located to detect any radiation escaping from the irradiator door, and (d) shall be located so that it is visible to the irradiator user when he is next to the irradiator.
4. If a room monitor is not installed, a survey meter shall be used (a) to determine the radiation level at the irradiator door when the door is closed, and (b) to check for any increase in radiation levels each time the irradiator door is opened. In conducting such checks, operators shall position themselves so as to minimize exposure to any radiation escaping from the open door.
5. If abnormal radiation levels or any malfunction of the irradiator are detected at any time, the licensee shall stop use of the irradiator and immediately notify the appropriate NRC regional office by telephone.
6. The licensee shall not attempt repair or authorize others to attempt repair of the irradiator except as specifically authorized in a license issued by NRC.

III

Any affected licensee may request a hearing on this Order. A request for a hearing shall be submitted within twenty (20) days of the date of this Order to Mr. R. E. Cunningham, Director, Division of Fuel Cycle and Material Safety, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, with a copy to the Executive Legal Director, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555. ANY REQUEST FOR A HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

IV

If a hearing is requested, the Commission will issue an Order designating the time and place of any such hearing. If a hearing is held the issue to be considered at such a hearing will be: Whether, on the basis of the matters set forth in Section 1 and II of this Order, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Richard E. Cunningham, Director
Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards

Dated at Bethesda, Maryland this 3rd day of July, 1984

Appendix F

Guidance on Financial Assurance

Guidance on Financial Assurance

Determining Need for Financial Assurance

If the only radioactive materials possessed are sealed sources in self-shielded irradiators, use **Table 6** to determine if financial assurance is required.

Table 6.
Worksheet for Determining Need for Financial Assurance for Self-Shielded Irradiators

Step No.	Description	Cobalt-60	Cesium-137	Strontium-90
1	Activity possessed, in Curies*			
2	Activity requiring financial assurance, in Curies	10,000	100,000	1,000
3	Divide data in Step 1 by data in Step 2 = FRACTION			
4	Add the fractions determined in Step 3			

*For ease of use by most irradiator licensees, this table uses only conventional units. The conversion to SI units is: 1 Ci = 37 GBq.

If the sum of the fractions is greater than or equal to 1, the applicant will need to submit certification of financial assurance or a decommissioning funding plan (**12VAC5-481-450 C**). NRC RG 3.66,(4) "*Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72*", dated June 1990, provides sample documents for financial mechanisms. The recommended wording for a Statement of Intent for government licensees is shown below.

Note: NRC RG 3.66 is available electronically at NRC's web site, <http://www.nrc.gov>.

Suggested Wording for a Statement of Intent for a Government Licensee

[date]

[name and address]

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

STATEMENT OF INTENT

As [Title] of [Licensee Name], I exercise express authority and responsibility to approve funding for decommissioning activities associated with operations authorized by Virginia Department of Health Material License No. [License Number]. This authority is established by [Name of Document(s) Governing Control of Funds]. Within this authority, I intend to have funds made available when necessary in an amount up to [Dollar Amount] to decommission [Description of Facilities]. I intend to request and obtain these funds sufficiently in advance of decommissioning to prevent delay of required activities.

A copy of [Name of Documents] is attached as evidence that I am authorized to represent [Licensee Name] in this transaction.

[SIGNATURE]

[NAME]

[TITLE]

Attachment: As stated

Appendix G

Training Program for Authorized Users and Radiation Safety Officers

Training Program for Authorized Users and Radiation Safety Officers

Course Content

Training may be in the form of lecture, videotape, hands-on, or self-study, and emphasizes practical subjects important to the safe use of the self-shielded irradiator:

- Radiation Safety
 - Radiation vs. contamination
 - Internal vs. external exposure
 - Biological effects of radiation
 - Types and relative hazards of radioactive material possessed
 - ALARA concept
 - Use of time, distance, and shielding to minimize exposure
 - Use of radiation detection instruments.

- Regulatory Requirements
 - Locations of use and storage of radioactive materials
 - Material control and accountability
 - Annual audit of radiation safety program
 - License conditions, amendments, renewals
 - Transfer and disposal
 - Recordkeeping
 - Handling incidents
 - Licensing and inspection by regulatory agency
 - Need for complete and accurate information
 - Employee protection
 - Deliberate misconduct.

- Practical Explanation of the Theory and Operation for Each Irradiator Possessed by the Licensee
 - Routine vs. non-routine maintenance
 - Operating and emergency procedures
 - Prior events involving self-shielded irradiators.

Instructor's Qualifications

The individual preparing and conducting training is qualified as Radiation Safety Officer (RSO) or Authorized User (AU) on a self-shielded irradiator license before giving training.

Training Assessment

Management will ensure that potential RSOs and AUs are qualified to work independently with each type of the licensee's irradiators. This may be demonstrated by written or oral examination or by observation.

Appendix H

Typical Duties and Responsibilities of the Radiation Safety Officer

Typical Duties and Responsibilities of the Radiation Safety Officer

The RSO's duties and responsibilities include ensuring radiological safety and compliance with VDH and DOT regulations and the conditions of the license; see **Table 2**. Typically, these duties and responsibilities include ensuring the following:

- Activities involving licensed material that the RSO considers unsafe are stopped
- Radiation exposures are ALARA
- Posting of required documents, or a notice where the following documents can be found:
 - Required by **12VAC5-481-2260**:
12VAC5-481 'Virginia Radiation Protection Regulations' Part IV, 'Standards for Protection from Radiation' and Part X, 'Notices, Instructions and Reports to Workers; Inspections'; license documents; operating procedures; VDH Form, 'Notice to Employees'
- Development, distribution, implementation, and maintenance of up-to-date operating and emergency procedures
- Possession, installation, relocation, use, storage, repair, and maintenance of self-shielded irradiators are consistent with the limitations in the license, the SSDR Certificate(s), and manufacturer's written recommendations and instructions
- Safety consequences are analyzed before conducting any activities involving repair, use, maintenance, installation, or relocation, which were never previously analyzed
- Individuals installing, relocating, using, maintaining, or repairing self-shielded irradiators are trained and authorized (as described in the license application)
- Prospective evaluations are performed demonstrating that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or personnel monitoring devices are provided
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained
- Self-shielded irradiators are properly secured

- Documentation is maintained to demonstrate, 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 in **12VAC5-481-720**.
- Proper authorities are notified of incidents such as damage to or malfunction of self-shielded irradiators, fire, or theft
- Unusual occurrences involving the self-shielded irradiators (e.g., malfunctions or damage) are investigated, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken
- Radiation safety program audits are performed at least annually and documented
- When the licensee identifies violations of **12VAC5-481 'Virginia Radiation Protection Regulations'** or license conditions or program weaknesses, the licensee develops, implements, and documents corrective actions
- Licensed material is transported in accordance with all applicable DOT requirements
- Licensed material is disposed of properly
- Appropriate records are maintained
- Up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner

Appendix I

Information Needed to Support Applicant's Request to Perform Non-Routine Maintenance

Information Needed to Support Applicant's Request to Perform Non-routine Maintenance

Review **Item 9.8** 'Maintenance' which discusses, in general, licensee responsibilities before any maintenance or repair is performed.

Non-routine maintenance includes repairs, removal, replacement, or alterations involving:

- Electrical and mechanical systems and components that control source or shielding movement
- Self-shielded irradiator's shielding or sealed source(s)
- Safety interlocks
- Any other component which may affect safety operation of the device
- Any other activities during which personnel could receive radiation doses exceeding VDH limits

If this maintenance or repair is not performed properly with attention to radiation safety principles, the self-shielded irradiator may not operate as designed and personnel performing these tasks could receive radiation doses exceeding VDH limits. Non-routine maintenance should be performed only by qualified and specifically authorized individuals. Self-shielded irradiator licensees should conduct these operations only after their procedures have been evaluated and specifically approved by license condition. Also, any non-manufacturer- (non-distributor-) supplied replacement components or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer (or distributor) needs to be evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration. Licensees also need to ensure that, after maintenance or repair is completed, the irradiator is tested and functions as designed, before the unit is returned to routine use.

Accordingly, applicants wishing to perform non-routine maintenance must provide the following information, as appropriate:

- Describe the types of non-routine maintenance to be performed. The principal reason for obtaining this information is to assist in the evaluation of the qualifications of individuals who will conduct the work and the radiation safety procedures they will follow.
- Identify who will perform non-routine maintenance, their training and experience, and why they are competent to perform non-routine maintenance. Adequate training and experience includes the following:
 - Previous experience in non-routine maintenance and radiation safety training
 - Vender maintenance certification
 - Technician(s) using pre-planned procedures with direct health physics supervision
- Submit procedures for non-routine maintenance. These procedures should ensure the following:
 - Doses to personnel and members of the public are within regulatory limits and ALARA
 - The source is secured against unauthorized access or removal
 - Appropriate labels and signs are used
 - Manufacturer's (distributor's) written instructions and recommendations are followed

- Any non-manufacturer (non-distributor) supplied replacement components or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer (or distributor) are evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration
 - Before being returned to routine use, the self-shielded irradiator is tested to verify that it functions as designed and source integrity is not compromised.
- Confirm that individuals performing non-routine maintenance on irradiators will always wear both whole body and extremity monitoring devices
 - Verify possession of at least one instrument that meets the description for survey meters used with moving-source irradiators in 'Radiation Monitoring Instrument Specifications and Survey Instrument Calibration Program' section of **Appendix K**.
 - Describe steps to be taken to ensure that radiation levels in areas where non-routine maintenance will take place do not exceed **12VAC5-481-720** limits. For example, applicants can do the following:
 - Commit to performing surveys with a survey instrument (as described above);
 - Specify where and when surveys will be conducted during non-routine maintenance; and
 - Commit to maintaining, for 3 years for the date of the survey, records of the survey (e.g., who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements), as required by **12VAC5-481-1050**.

Appendix J

Self-Shielded Irradiator Audit Checklist

Self-Shielded Irradiator 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 _____

Auditor: _____
(Signature)

Date _____

Management Review _____
(Signature)

Date _____

Audit History

- A. Were previous audits conducted annually? [12VAC5-481-630]
- B. Where records of previous audits maintained? [12VAC5-481-990]
- C. Were any deficiencies identified during last two audits or two years, whichever is longer?
- D. Were corrective actions taken? (Look for repeated deficiencies).

Organization and Scope of Program

- A. Radiation Safety Officer
 - 1. If the RSO was changed, was license amended?
 - 2. Does new RSO meet VDH training requirements?
 - 3. Is RSO fulfilling his/her duties?
 - 4. To whom does RSO report?

B. Licensed Material

1. Does the license authorize all of the VDH-regulated radioactive material contained in self-shielded irradiators?
 2. Does the total amount of radioactive material possessed require financial assurance?
[12VAC5-481-450 C]
- C. Are the self-shielded irradiators as described in the Sealed Source and Device Registration (SSDR) Certificate? Have copies of (or access to) SSDR Certificates? Have manufacturer's (or distributor's) manuals for operation and maintenance?
- D. Are the actual uses of self-shielded irradiators consistent with the authorized uses listed on the license?
- E. If the mailing address or places of use changed, was the license amended?
- F. If control of license transferred or bankruptcy filed, was agency prior consent obtained or notification made, respectively?

Training and Instructions to Workers

- A. Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed per 12VAC5-481-2270? Was refresher training provided, as needed [12VAC5-481-2270]?
- B. Did each authorized user and person independently performing routine or non-routine maintenance attend license-required training before working with self-shielded irradiators?
- C. Are training records maintained for each individual?
- D. Did interviews with workers reveal that they know the emergency procedures and repair, maintenance, and relocation limitations?
- E. Did this audit include observations of operators using the self-shielded irradiators? Performing routine or other authorized maintenance?
- F. Did the audit identify any operator error in reporting maintenance and repair or operation issues to the RSO for review before starting work?

Radiation Survey Instruments

- A. Describe the survey instruments possessed:
 1. Do they meet the agency's criteria?

2. Are they appropriate for the source type(s)?
 3. Are they checked for function before use?
 4. If they are used with moving-source irradiators or during non-routine maintenance, are they calibrated as required? [12VAC5-481-750]
- B. If the licensee does not possess a survey meter, are specific plans made to have one available?

Location: _____ Location/Operation verified: _____

- C. Are calibration records, if required, maintained? [12VAC5-481-1000]
- D. For J. L. Shepherd Mark I or Model 81-22 irradiator, check for compliance with license condition

Self-Shielded Irradiator Inventory and Location

- A. Is a record kept showing the receipt of each self-shielded irradiator? [12VAC5-481-100, 12VAC5-481-571]
- B. Has the location(s) changed since the last audit?

Personnel Radiation Protection

- A. Are ALARA considerations incorporated into the radiation protection program? [12VAC5-481-630]
- B. Were prospective evaluations performed showing that unmonitored users receive $\leq 10\%$ of limit? [12VAC5-481-760]
- C. Did unmonitored users' activities change during the year which could put them over 10% of limit?
- D. If yes to C above, was a new evaluation performed?
- E. Is external dosimetry required (users received $>10\%$ of limit)? Is dosimetry provided to users?
1. If processed dosimetry:
 - a. Is the dosimetry supplier NVLAP-approved? [12VAC5-481-750]

- b. Are dosimetry reports reviewed by the RSO when they are received?
2. If self-reading dosimeters:
- a. Have a range of zero to at least 2 mSv (200 mrem)?
 - b. Are checked at periods not to exceed one year for correct response to radiation?
 - c. Are read within $\pm 20\%$ of the true radiation exposure?
 - d. Are used under a program that prescribes action to evaluate the individual's dose?
- F. Are the dosimeters exchanged or read at the license required frequency?
- G. Are the records agency forms or equivalent? [12VAC5-481-1000, 12VAC5-481-1040]
- 1. VDH Form, 'Occupational Exposure Record per Monitoring Period' completed?
- H. Declared pregnant worker/embryo/fetus
- 1. If a worker declared her pregnancy, did licensee comply with 12VAC5-481-710?
 - 2. Were records kept of embryo/fetus dose per 12VAC5-481-1040?
- I. Are records of exposures, surveys, monitoring, and evaluations maintained?
[12VAC5-481-990, 12VAC5-481-1000, 12VAC5-481-1020, 12VAC5-481-1030, 12VAC5-481-1040, 12VAC5-481-1050]
- J. Are annual exposure reports given to workers who receive > 100 mrem per year? [12VAC5-481-2280]

Public Dose

- A. Are self-shielded irradiators located and used in a manner to keep doses below 1 mSv (100 mrem) in a year? [12VAC5-481-720]
- B. Has a survey or evaluation been performed per 12VAC5-481-730?
- C. Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?

- D. Do unrestricted area radiation levels exceed 0.02 mSv (2 mrem) in any one hour?
[12VAC5-481-720]
- E. Are self-shielded irradiators being used or stored in a manner that would prevent unauthorized access or removal? [12VAC5-481-840]
- F. Records maintained? [12VAC5-481-1000, 12VAC5-481-1050]

Operating and Emergency Procedures

- A. Have operating and emergency procedures been developed?
- B. Do they contain the required element?
- C. Does each operator have a current copy of the operating and emergency procedures? Maintain copy at each irradiator's control panel or post notice indicating where to obtain copy?
- D. Did any emergencies occur?
 - 1. If so, were they handled properly by operator?
 - 2. Were appropriate corrective actions taken?
 - 3. Was agency notification or reporting required? [12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1150]
- E. For J. L. Shepherd Mark I or Model 81-22 irradiator, check for compliance with license condition
- F. Were operating or emergency procedures changed since last audit? If so, before new procedures were implemented:
 - 1. Did licensee management and the RSO approve?
 - 2. Did affected staff receive training?
 - 3. Are the changes consistent with license conditions? Licensee commitments?
 - 4. Do the changes degrade safety?

Leak Tests

- A. Was each sealed source leak tested every 6 months (or at other license prescribed intervals)?
- B. Was the leak test performed as described in correspondence with VDH and according to the license?
- C. Are records of results retained with the appropriate information included?
- D. Were any sources found leaking and if yes, was the agency notified?

Maintenance of Self-shielded Irradiators

- A. Are manufacturer's (or distributor's) written procedures followed for routine (not safety critical) cleaning and lubrication and mechanical/electrical maintenance and repair of self-shielded irradiators?
- B. Was non-routine maintenance performed?
- C. If yes, was it performed according to license requirements (e.g., extent of work, individuals performing the work, procedures, dosimetry, survey instrument, compliance with dose limits)?
- D. Since the last audit, did operator(s) report a need for non-routine maintenance and repair to the RSO before requesting or conducting the work?

Transportation

- A. Were self-shielded irradiator(s) or sources shipped since the last audit?
- B. If so, was **12VAC5-481 'Virginia Radiation Protection Regulations' Part XIII 'Transportation of Radioactive Material'** requirements followed?
 - 1. DOT-Type A or Type B packages used? [**12VAC5-481 'Virginia Radiation Protection Regulations' Part XIII, 49 CFR 173.415, 49 CFR 173.416(b)**] If Type B, NRC Certificate of Compliance granted before shipment or shipper is registered as a user of the Type B package? VDH-approved QA program? [**12VAC5-481-3130**]
 - 2. Package performance test records on file? [**49 CFR 173.415**]
 - 3. Special form sources documentation? [**49 CFR 173.476(a)**]
 - 4. Package has 2 labels (ex. Yellow-II) with TI, Nuclide, Activity, and Hazard Class? [**49 CFR 172.403; 49 CFR 173.441**]

5. Package properly marked? [49 CFR 172.301; 49 CFR 172.304; 49 CFR 172.310; 49 CFR 172.324]
6. Package closed and sealed during transport? [49 CFR 173.475(f)]
7. Shipping papers prepared, used, and maintained? [49 CFR 172.200(a)]
8. 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, Cargo Aircraft Only (If applicable)} [49 CFR 172.200; 49 CFR 172.201; 49 CFR 172.202; 49 CFR 172.203; 49 CFR 172.204; 49 CFR 172.604]
9. Secured against movement? [49 CFR 177.834]
10. Placarded on vehicle, if needed? [49 CFR 172.504]
11. Proper overpacks, if used? [49 CFR 173.25]
12. Any incidents reported to DOT? [49 CFR 171.15; 49 CFR 171.16]
13. Irradiators manufactured before 1966
 - a. Where any shipped?
 - b. Were VDH and DOT exemptions, if needed, received in advance?

Auditor's Independent Survey Measurements (If Made)

- A. Describe the type, location, and results of measurements.
- B. Do any radiation levels exceed regulatory limits?

Notifications 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? [12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1150]
- C. Did any overexposures and high radiation levels occur? Reported? [12VAC5-481-1100, 12VAC5-481-1110]
- D. If any events (as described in 1 through 3 above) did occur, what was root cause? Were corrective actions appropriate?
- E. Is the licensee aware of 24-hr VDH emergency telephone number [(804) 674-2400 or (800) 468-8892]?

Posting and Labeling

- A. VDH Form, 'Notice to Employees' posted? [12VAC5-481-2260 C]
- B. 12VAC5-481 'Virginia Radiation Protection Regulations', license documents posted or a notice posted? [12VAC5-481-2260 A]
- C. Other posting and labeling? [12VAC5-481-850, 12VA5-481-860, 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?

Bulletins and Information Notices

- A. Agency Bulletins and/or Information Notices received?
- B. Appropriate training and action taken in response?

Special License Conditions or Issues

- A. Did auditor review any special license conditions?
- B. Did auditor review any other issues (e.g., non-routine maintenance)?

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. 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 Radiation Safety Officer (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 K

Radiation Monitoring Instrument Specifications and Survey Instrument Calibration Program

Survey Instrument Calibration Program

Instrument(s) used with moving-source gamma irradiators must meet the following criteria:

- The instrument is a survey meter capable of detecting gamma radiation of more than 5×10^{-5} coulombs/kilogram (C/kg) (or up to several hundred milliroentgens (mR)) per hour which is:
 - In the licensee's possession
 - Checked with a source of radiation at the beginning of each day of use to ensure that it will respond consistently to radiation
 - Calibrated with a source of radiation annually and after any servicing or repair (other than a simple battery exchange), ensure that exposure rates indicated by the meter do not vary from the actual exposure rates by more than $\pm 20\%$. Calibrations must be performed by the instrument manufacturer or a person specifically authorized by VDH, the NRC, or another Agreement State.

OR

- The instrument is a room monitor which:
 - Is in the licensee's possession
 - Is checked with a source of radiation at the beginning of each day of use to ensure that it will respond accurately to radiation and alarm at 0.02 mSv (2 mrem) per hour
 - Activates a visible and audible alarm when radiation levels exceed 0.02 mSv (2 mrem) per hour
 - Is positioned so it will detect any radiation escaping from the irradiator door yet still be visible to the irradiator operator when using the irradiator.

Instrument(s) used with fixed-source gamma irradiators (or beta irradiators) are:

- A survey meter capable of detecting gamma radiation (or beta radiation, as appropriate)
- In the licensee's possession or readily accessible in the event of an accident or malfunction which could reduce the shielding for the sealed source(s)
- Checked with a source of radiation at the beginning of each day of use to ensure that it will respond consistently to radiation
- Calibrated with a source of radiation annually and after any servicing or repair (other than a simple battery exchange), to ensure that exposure rates indicated by the meter do not vary from the actual exposure rates by more than $\pm 20\%$. Calibrations must be performed by the instrument manufacturer or a person specifically authorized by VDH, the NRC or another Agreement State.

Training

Before allowing an individual to perform survey instrument calibrations, the RSO will ensure that the individual has sufficient classroom and on-the-job training to show competency in performing independent survey instrument calibrations.

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

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

Appropriate on-the-job training consists of:

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

Facilities and Equipment

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

Procedures for Calibrating Survey Instruments for Gamma Detection

- A radioactive sealed source(s) used for calibrating survey instruments will:
 - Approximate a point source
 - Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified to be within $\pm 5\%$ accuracy by NIST
 - Approximately the same photon energy (Cs-137, Co-60) as the environment in which the calibrated device will be employed
 - Be strong enough to give an exposure rate of at least 7.7×10^{-6} C/kg/hr (or 30 mR/hr) at 100 cm [e.g., 3.1 GBq (85 mCi) of Cs-137) or 7.8×10^2 MBq (21 mCi) of Co-60].
- The inverse square and radioactive decay laws must be used to correct changes in exposure rate due to changes in distance or source decay.
- A record must be made of each survey meter calibration and retained for 3 years after each record is made (12VAC5-481-1000)

- A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than $\pm 20\%$
- The three kinds of scales frequently used on radiation survey meters are calibrated either as described in ANSI N323A-1996, "*American National Standard Radiation Protection Instrumentation Test and Calibration- Portable Survey Instruments*", or as follows:
 - Meters on which the user selects a linear scale must be calibrated at not fewer than two points on each scale. The points will be at approximately 1/3 and 2/3 of the decade.
 - Meters that have a multidecade logarithmic scale must be calibrated at one point (at the least) on each decade and not fewer than two points on one of the decades. Those points will be approximately 1/3 and 2/3 of the decade
 - Meters that have an automatically ranging digital display device for indicating exposure rates must be calibrated at one point (at the least) on each decade and at no fewer than two points on one of the decades. Those points will be approximately 1/3 and 2/3 of the decade.
- Readings above 2.58×10^{-4} C/kg/hr (1000 mR/hr) need not be calibrated. However, such scales should be checked for operation and approximately correct response.
- Survey meter calibration reports 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 on a specified date, and the calibration procedure
 - For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument
 - The exposure reading indicated with the instrument in the 'battery check' mode (if available on the instrument)
 - For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)
 - For instruments with internal detectors, the angle between 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 from a check source, if used
 - The person's name who performed the calibration and date it was performed
- The following information will be attached to the instrument as a calibration sticker or tag:
 - The source that was used to calibrate the instrument
 - The proper deflection in the battery check mode (unless this is clearly indicated on the instrument)
 - For each scale or decade not calibrated, an indication that the scale or decade was checked on for function but not calibrated

- The date of calibration and the next calibration due date
- The apparent exposure rate from the check source, if used.

References: Detailed information about survey instrument calibration may be obtained by referring to ANSI N323A-1996, *"American National Standard Radiation Protection Instrumentation Test and Calibration - Portable Survey Instruments"*. Copies may be ordered electronically at <http://www.ansi.org> or by writing to: ANSI, 1430 Broadway, New York, NY 10018. See Section 8.10.2 and Appendix J of NRC NUREG 1556 Vol. 18 *"Program Specific Guidance about Service Provider Licenses"*, and is available electronically at NRC's web site, <http://www.nrc.gov>.

Appendix L

Guidance for Demonstrating That Unmonitored Individuals Are Not Likely to Exceed 10 Percent of the Allowable Limits

Guidance for Demonstrating That Unmonitored Individuals Are Not Likely to Exceed 10 Percent of the Allowable Limits

Dosimetry is required for individuals likely to receive, in 1 year from sources external to the body, a dose in excess of 10% of the applicable regulatory limits in 12VAC5-481-640, 12VAC5-481-700, and 12VAC5-481-710. To demonstrate that dosimetry is not required, a licensee needs to perform a prospective evaluation to demonstrate that its workers are not likely to exceed 10% of the applicable annual limits.

The most common way that individuals might exceed 10% of the applicable limits is by performing frequent routine maintenance on the irradiator. However, for most new irradiators even these activities result in the individual's receiving minimal doses. Before allowing workers to perform these tasks, a licensee will need to evaluate the doses which its workers might receive to assess whether dosimetry is required; this is a prospective evaluation.

Example

The following is an example of an estimate of the dose received by the extremities and whole body of a person performing routine maintenance (cleaning and lubrication) on a self-shielded irradiator rotating drawer drive chain. The estimate is based on observations of individuals performing the recommended procedure according to good radiation safety practices. The manufacturer can provide the following types of information:

- Time needed to perform the entire procedure (e.g., 20 min)
- Extremity dose rate received by an individual, associated with the shielded source (e.g., 0.02 mSv/hr [2 mrem/hr] at contact with the shield)
- Time the hands were exposed to the shielded source (e.g., 3 min)
- Whole body dose rate received by an individual, associated with the shielded source (e.g., 0.01 mSv/hr [1 mrem/hr] at contact with the shield)
- Time the whole body is exposed to the shielded source (e.g., 20 min)

From this information, an estimate of the doses that the individual performing this procedure could receive is as follows:

- 0.001 mSv [0.1 mrem] to the hands
- Less than 0.0033 mSv [0.33 mrem] TEDE (whole body).

The applicable TEDE (whole body) limit is 50 mSv (5 rems) per year and 10% of that value is 5 mSv (500 mrems) per year. If one of these procedures delivers 0.0033 mSv (0.33 mrem), then an individual could perform 1,515 of these procedures each year and remain within 10% of the applicable limit.

The applicable shallow-dose equivalent (SDE) (extremities) is 500 mSv (50 rems) per year and 10% of that value is 50 mSv (5 rems or 5000 mrem) per year. If one of these procedures delivers 0.001 mSv (0.1 mrem), then an individual could perform 50,000 of these procedures each year and remain within 10% of the applicable limit.

Based on the above specific situation, no dosimetry is required if a worker performs fewer than 1,515 routine maintenance procedures per year.

Guidance to Licensees

Licensees who wish to demonstrate that they are **not** required to provide dosimetry to their workers need to perform prospective evaluations similar to that shown in the example above. The expected dose rates, times, and distances used in the above example may **not** be appropriate to individual licensee situations. In their evaluations, licensees need to use information appropriate to the type(s) of self-shielded irradiator(s) they intend to use; this information is generally available from the irradiator manufacturer (or distributor) or the SDR Certificate maintained by VDH, the NRC and other Agreement States.

Table 7 may be helpful in performing a prospective evaluation.

<p>Note: For ease of use by most irradiator licensees, this table uses conventional units. The conversion to SI units is: 1 mrem = 0.01 mSv.</p>

Licensees should review evaluations periodically and revise them as needed. Licensees need to check assumptions used in their evaluations to ensure that they continue to be up-to-date and accurate. For example, if workers become lax in following good radiation safety practices, perform the task more slowly than estimated, work with new irradiators containing sources of different activities or radionuclides, or use modified procedures, the licensee would need to conduct a new evaluation.

Table 7. Dosimetry Evaluation

Dosimetry Evaluation for :		Model:	Self-Shielded Irradiator	
A.	Time needed to perform the entire routine maintenance procedure.		____ (min./60)	____ hour
B.	Expected whole body dose rate received by the individual, determined using exposure rates measured on contact with the irradiator while the sealed source is in the shielded position.		____ mrem/hr	
C.	Time the hands were exposed to the unshielded source.		____ (min./60)	____ hour
D.	Expected extremity dose rate received by the individual, determined using exposure rates measured at the typical distance that the hands would be from the sealed source during the routine maintenance procedure.		____ mrem/hr	

Formula: (____ # hours in Row A) x (____ mrem/hr in Row B) = (____ mrem per routine procedure) x (____ # of routine maintenance procedure each year) = ____ mrem * Whole Body Dose

Formula: (____ # hours in Row C) x (____ mrem/hr in Row D) = (____ mrem per routine procedure) x (____ # of routine maintenance procedures each year) = ____ mrem
**** Extremity Dose**

* Expected Whole Body Doses *less than* 500 mrem requires no dosimetry
 ** Expected Extremity Doses *less than* 5000 mrem requires no dosimetry

Appendix M

Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 mSv (100 mrem) in one calendar year resulting from the licensee's possession and/or use of licensed materials.

Members of the public include persons who live, work, or may be near locations where self-shielded irradiator devices are used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where irradiators are used or stored.

- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.

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

Licensees must show compliance with both portions of the regulation. For areas around self-shielded irradiator facilities, calculations or a combination of calculations and measurements (e.g., using an environmental TLD) are often used to prove compliance.

Calculation Method

The calculation method takes a tiered approach, going through a three-part process starting with a worst case situation and moving toward more realistic situations. It makes the following simplifications: (1) each irradiator is a point source; (2) typical radiation levels encountered when the source is in the shielded position are taken from either the SDR Certificate, ANSI N433.1, (7) *"Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiator (Category I)"*, or the manufacturer's (or distributor's) literature; and (3) no credit is taken for any shielding found between the irradiator and the unrestricted areas.

Note: Copies may be ordered electronically at <http://www.ansi.org> or by writing to ANSI, 1430 Broadway, New York, NY 10018. Copies are also available from the NTIS, 5285 Port Royal Road, Springfield, VA 22161 1-800-553-6847.

Part 1 of the calculation method is simple but conservative. It assumes that an affected member of the public is present 24 hours a day and uses only the inverse square law to determine if the distance between the irradiator and the affected member of the public is sufficient to show compliance with the public dose limits. **Part 2** considers not only distance, but also the time that the affected member of the public is actually in the area under consideration. **Part 3** considers the distance, the portion of time and dose rate while the sample is in transit, the portion of time and dose rate while the sample is not in transit, and the portion of time that the affected member of the public is present. Using this approach, licensees make only those calculations that are needed to demonstrate compliance. In many cases licensees will need to use the calculation method through **Part 1** or **Part 2**. The results of these calculations typically result in higher radiation levels than would exist at typical facilities, but provide a conservative method for estimating doses which could be received.

Example 1

To better understand the calculation method, we will examine Bugs-Away, Inc., a self-shielded irradiator licensee. Yesterday, the company's president noted that the new irradiator area is close to his secretary's desk and he asked Joe, the Radiation Safety Officer (RSO), to determine if the company is complying with **12VAC5-481-720**.

The secretary's desk is near the wall separating the reception area from the designated, locked self-shielded irradiator room where the company has located its irradiator. Joe measures the distance from the self-shielded irradiator to the wall and assumes that the irradiator would have the maximum dose rate allowed under ANSI N433.1 of 10 mrem per hour at one meter. This is the maximum dose rate permitted while the sample is in transit (i.e., moving into or out of the irradiation position). Joe uses this information to determine the dose rate in mrem/hr at a specified distance from the irradiator determined to be 10 mrem/hr at 1 meter (3.28 ft). He also determines that the secretary's chair is 15 feet from the irradiator.

Example 1: Part 1

Joe's first thought is that the distance between the irradiator and the secretary's chair may be sufficient to show compliance with the regulation in **12VAC5-481-720**. So, taking a worst case approach, he assumes: 1) the self-shielded irradiator is constantly present (i.e., 24 hr/d) with the samples constantly in transit, and 2) the secretary is constantly sitting in the desk chair (i.e., 24 hr/d). Joe proceeds to calculate the dose she might receive hourly and yearly from the self-shielded irradiator as shown in **Table 8** below.

Table 8. Calculation Method, Part 1: Hourly and Annual Dose Received from Self-Shielded Irradiator

Step No.	Description	Input Data	Result
1	Dose received in an hour at known distance from irradiator (e.g., from ANSI N433.1), in mrem/hr	10	10
2	Square of the distance (ft) at which the Step 1 rate was measured, in ft ²	(3.28) ²	10.8
3	Square of the distance (ft) from the irradiator to the secretary's desk in an unrestricted area in ft ²	(15.0) ²	225
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	10 x 10.8	108 (rounded to 110)
5	Divide the results of Step 4 by the result of Step 3 to calculate the dose received by an individual at the secretary's desk, HOURLY DOSE RECEIVED FROM SELF-SHIELDED IRRADIATOR , in mrem in an hour	110/225	0.48
6	Multiply the result of Step 5 by 24 hr/d x 366 (leap year) d/yr = MAXIMUM ANNUAL DOSE RECEIVED FROM SELF-SHIELDED IRRADIATOR , in mrem in a year	0.48 x 24 x 366	4200

Note: The result in Step 5 demonstrates compliance with the 2 mrem in any one hour limit. Reevaluate if assumption change. If the result in Step 6 exceeds 100 mrem/yr, proceed to Part 2 of the calculation method.

At this point, Joe is pleased to see that the total dose that an individual could receive in any one hour is only 0.48 mrem, but notes that an individual could receive a dose of 4,200 mrem in a year, much higher than the 100 mrem limit.

Example 1: Part 2

Joe reviews his assumptions and recognizes that the secretary is not at the desk 24 hr/d. He decides to make a realistic estimate of the number of hours the secretary sits in the chair at the desk, keeping his other assumptions constant (i.e., the self-shielded irradiator is constantly present (i.e., 24 hr/d) with the samples constantly in transit). He then recalculates the annual dose received.

Table 9. Calculation Method, Part 2: Annual Dose Received from Self-Shielded Irradiator

Step No.	Description	Result
7	A. Average number of hours per day that individual spends in area of concern (e.g., secretary sits at desk 5 hr/d; the remainder of the day the secretary is away from the desk area copying, filing, etc.)	5.0
	B. Average number of days per week in area (e.g., secretary is part time and works 3 d/wk)	3.0
	C. Average number of weeks per year in area (e.g., secretary works all year)	52
8	Multiply the results of Step 7.A by the results of Step 7.B. by the results of Step 7.C. = AVERAGE NUMBER OF HOURS IN AREA OF CONCERN PER YEAR	$5.0 \times 3.0 \times 52 = 780$
9	Multiply the results in Step 5 by the results of Step 8 = ANNUAL DOSE RECEIVED FROM IRRADIATOR CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN, in mrem in a year	$0.48 \times 780 = 370$

Note: If Step 9 exceeds 100 mrem in a year, proceed to Part 3 of the Calculation method.

Although Joe is pleased to note that the calculated annual dose received is significantly lower, he realizes it still exceeds the 100 mrem in a year limit.

Example 1: Part 3

Again, Joe reviews his assumptions and recognizes that the irradiator is not constantly in use nor is the sample continuously in transit during an irradiation cycle when the secretary is seated at the desk. As he examines the situation, he realizes he must take these factors into account.

First, he realizes that while the irradiator is in transit, the dose rate at 3.28 feet is 10; however, when it is idle or when a sample is irradiated, the dose rate at 3.28 feet is reduced to 2 mrem/hr. The maximum number of irradiations per hour is 5 with a 3 minute maximum irradiation time. The time the sample is in transit per irradiation cycle is also 0.2 minutes. Referring to previous information, he takes into account that the secretary's chair is 15 feet away from the irradiator and the secretary is present for 780 hours per year.

Table 10. Calculation Method, Part 3: Annual Dose Received from Irradiator

Step No.	Description	Result
18	[60 minus the input from Step 13 multiplied by (the input from Step 14 plus the input from Step 15) divided by 60 = $[60. - 5.0 \times (3.0 + 0.20)] / 60. = [60. - 16.] / 60 =$ FRACTION OF TIME THE IRRADIATOR IS IDLE	0.73
19	(The input from Step 13 multiplied by the input from Step 15) divided by 60 = $(5.0 \times 0.20) / 60 = 1/60 =$ FRACTION OF TIME THE SAMPLE IS IN TRANSIT	0.017
20	1.0 minus the result from Step 18 minus the result from Step 19 = $1 - 0.73 - 0.017 =$ FRACTION OF TIME THE IRRADIATOR IS IN USE	0.253
21	(The input from Step 10 multiplied by the result from Step 18) plus (the input from Step 11 multiplied by the result from Step 19) plus (the input from Step 12 multiplied by the result from Step 20) = $(2.0 \times 0.73) + (10. \times 0.017) + (2.0 \times 0.253) = 1.46 + 0.17 + 0.506 =$ AVERAGE DOSE RATE ENCOUNTERED AT 3.28 FEET FROM THE IRRADIATOR, in mrem in an hour	2.136
22	The result from Step 21 multiplied by (3.28 squared divided by the input from Step 16 squared) = $2.136 \times (3.28^2 / 15^2) = 2.136 \times (10.8/225) =$ AVERAGE DOSE RATE ENCOUNTERED BY THE SECRETARY, in mrem per hour	0.10
23	The result from Step 22 multiplied by the input from Step 17 = $780 \times 0.10 =$ ANNUAL DOSE RECEIVED FROM IRRADIATOR CONSIDERING REALISTIC ESTIMATES FOR TIME SPENT IN AREA OF CONCERN, DOSE RATES, AND IRRADIATOR USAGE, in mrem in a year	78.

Note: If the result in Step 23 is greater than 100 mrem/yr, the licensee must take corrective actions

Joe is glad to see that the results in Step 23 show compliance with the 100 mrem in a year limit. Had the result in Step 23 been higher than 100 mrem in a year, then Joe could have done one or more of the following:

- Consider whether the assumptions used to determine occupancy are accurate, revise the assumptions as needed, and recalculate using the new assumptions
- Calculate the effect of any shielding located between the irradiator area and the secretarial workstation -- such calculation is beyond the scope of this Appendix
- Take corrective action (e.g., move irradiator within the use area, move the use area, move the secretarial workstation) and perform new calculations to demonstrate compliance

- Designate the area outside the use area as a restricted area and the secretary as an occupationally exposed individual. This would require controlling access to the area for purposes of radiation protection and training the secretary.

Note: National Council on Radiation Protection and Measurements (NCRP) Report No. 49, "*Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV*", contains helpful information. It is available from NCRP, 7910 Woodmont Avenue, Suite 800, Bethesda, Maryland 20814. NCRP's telephone numbers are: (301) 657-2652 or 1-800-229-2652.

Note that in the example, Joe evaluated the unrestricted area outside only one wall of the irradiator area. Licensees also need to make similar evaluations for other unrestricted areas and to keep in mind the ALARA principle, taking reasonable steps to keep radiation dose received below regulatory requirements. In addition, licensees need to be alert to changes in situations (e.g., moving the self-shielded irradiator closer to the secretarial workstation, adding a second irradiator, changing the secretary to a full-time worker, or changing the estimate of the portion of time spent at the desk) and to perform additional evaluations, as needed.

RECORDKEEPING: 12VAC5-481-1050 requires licensees to maintain records demonstrating compliance with the dose limits for individual members of the public.

Combination Measurement-Calculation Method

This method, which allows the licensee to take credit for shielding between the irradiator and the area in question, begins by measuring radiation levels in the areas, as opposed to using ANSI-N433.1 or manufacturer- (or distributor-) supplied rates at a specified distance from each irradiator. These measurements must be made with calibrated survey meters sufficiently sensitive to measure background levels of radiation. However, licensees must exercise caution when making these measurements, and they must use currently calibrated radiation survey instruments. A maximum dose of 1 mSv (100 mrem) received by an individual over a period of 2080 hours (i.e., a 'work year' of 40 hr/wk for 52 wk/yr) is equal to less than 0.5 microsievert (0.05 mrem) per hour.

This rate is well below the minimum sensitivity of most commonly available G-M survey instruments.

Instruments used to make measurements for calculations must be sufficiently sensitive. An instrument equipped with a scintillation-type detector (e.g., NaI(Tl)) or a micro-R meter used in making very low gamma radiation measurements should be adequate.

Licensees may also choose to use environmental TLDs (see note) in unrestricted areas next to the irradiator area for monitoring. This direct measurement method would provide a definitive measurement of actual radiation levels in unrestricted areas without any restrictive assumptions. Records of these measurements can then be evaluated to ensure that rates in unrestricted areas do not exceed the 1 mSv/yr (100 mrem/yr) limit.

Note: TLDs used for personnel monitoring (e.g., LiF) may not have sufficient sensitivity for this purpose. Generally, the minimum reportable dose received is 0.1 mSv (10 mrem). Suppose a TLD monitors dose received and is changed once a month. If the measurements are at the minimum reportable level, the annual dose received could have been about 1.2 mSv (120 mrem), a value in excess of the 1 mSv/yr (100 mrem/yr) limit. If licensees use TLDs to evaluate compliance with the public dose limits, they should consult with their TLD supplier and choose more sensitive TLDs, such as those containing CaF_2 that are used for environmental monitoring.

Example 2

As in Example 1, Joe is the RSO for Bugs-Away, Inc., a self-shielded irradiator licensee. The company has one irradiator in a designated, locked area that adjoins an unrestricted area where a secretarial workstation is located. Refer to previous Example 1 for additional information. Joe wants to see if the company complies with the public dose limits at the secretarial station.

Joe placed an environmental TLD badge in the secretarial work space for 30 days. The TLD processor sent Joe a report indicating the TLD received 100 mrem.

Table 11. Combination Measurement-Calculation Method

Step No.	Description	Input Data and Results
Part 1		
1	Dose received by TLD, in mrem	100
2	Total hours TLD exposed	24 hr/d x 30 d/mo = 720
3	Divide the results of Step 1 by the results of Step 2 = HOURLY DOSE RECEIVED , in mrem in an hour	100/720 = 0.14
4	Multiply the results of Step 3 by 366 d/yr [leap year] x 24 hr/d = 8784 hours in one year = MAXIMUM ANNUAL DOSE RECEIVED FROM IRRADIATOR , in mrem in a year	366 x 24 x 0.14 = 8784 x 0.14 = 1230

Note: For the conditions described above, Step 3 indicates that the dose received in any one hour is less than the 2 mrem in any one hour limit. However, if there are any changes, then the licensee would need to reevaluate the potential doses which could be received in any one hour. Step 4 indicates that the annual dose received would be much greater than the 100 mrem in a year allowed by the regulations

Part 2

At this point Joe can adjust for a realistic estimate of the time the secretary spends in the area as he did in Part 2 of Example 1.

Part 3

If the results of Joe's evaluation in Part 2 show that the annual dose received in a year exceeds 100 mrem, then he may have to consider moving the self-shielded irradiator or the secretary's desk, or adding shielding to the wall.

Appendix N

Typical Agency Incident Notifications Required for Self-Shielded Irradiator Licensees

VDH Incident Notifications

Table 12. Typical VDH Incident Notifications Required for Self-Shielded Irradiator Licensees

Event	Telephone Notification	Written Report	Rule Requirement
Theft or lost of material	Immediate	30 days	12VAC5-481-1090
Whole body dose greater than 0.25 Sv (25 rems)	Immediate	30 days	12VAC5-481-1100
Extremity dose greater than 2.5 Sv (25 rems)	Immediate	30 days	12VAC5-481-1100
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
Whole body dose greater than 0.05 Sv (5 rems)	None	30 days	12VAC5-481-1110
Dose to individual member of public greater than 1 mSv (100 mrem)	None	30 days	12VAC5-481-1110
Filing petition for bankruptcy under 11 U.S.C.	None	Immediately after filing petition	12VAC5-481-500 E & F
Expiration of license	None	60 days	12VAC5-481-510 D
Decision to permanently cease license activities at entire site	None	30 days	12VAC5-481-510 D
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 D
No principal activities conducted for 24 months at the entire site	None	60 days	12VAC5-481-510 D
No principal activities conducted for 24 months in any separate building or outdoor area that is unsuitable for release	None	60 days	12VAC5-481-510 D

Event	Telephone Notification	Written Report	Rule Requirement
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	Immediate	30 days	12VAC5-481-1100, 12VAC5-481-1110
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	12VAC5-481-1110
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	12VAC5-481-1110

Note: Telephone notifications shall be made to the agency at (804) 864-8150 (during office hours) or (804) 674-2400 or (800) 468-8892 (24-hour emergency number) if an emergency. Identify emergency as radiological.

Appendix O

Information for Applicants to Consider When Developing Operating and Emergency Procedures for Self-Shielded Irradiators

Elements of Operating and Emergency Procedures Applicable to All Types of Self-Shielded Irradiators

- Analyze each type of material to be placed in the irradiator to ensure that it is comparable with the irradiator's design or to determine whether special procedures in addition to those given by the manufacturer (or distributor) are required to ensure the safe operation of the irradiator.
- Prepare model-specific instructions for routine inspections, test procedures, and maintenance to ensure that all interlocks, devices, and components critical to the safe operation of the irradiator are functioning properly. (Prohibited actions such as changing the safety control system or removing the source should be stated.)
- Develop methods to maintain accountability (e.g., logbook to record irradiator use) and to ensure that only authorized persons will use or have access to the irradiator (e.g., control access to the irradiator's keys or control access to the area where the irradiator is located).
- Define steps to take to keep radiation exposures ALARA
- For each model irradiator, define step-by-step procedures on how to operate the irradiator and how to perform routine maintenance. Information may be extracted from the manufacturer's (or distributor's) manual.

Specific Operating Procedures Applicable to Moving-Source Irradiators

- The irradiator should not be used unless the licensee provides a calibrated and operable radiation survey meter or a room monitor for use with the irradiator.
- The irradiator door should not be opened until the operator has checked visual indicators to verify that the source has returned to its safe storage position.
- Each room monitor should:
 - Be operable at all times when the irradiator is in use
 - Activate a visible and audible alarm when radiation levels exceed 0.02 mSv (2 mrem) per hour
 - Be located to detect any radiation escaping from the irradiator door
 - Be located so that it is visible to the irradiator user when next to the irradiator

- If a room monitor is not installed, a survey meter should be used to:
 - Determine the radiation level at the irradiator door when the door is closed
 - Check for any increase in radiation levels each time the irradiator door is opened. In conducting such checks, operators should position themselves to minimize exposure to any radiation escaping from the open door.
 - If abnormal radiation levels or any malfunction of the irradiator are detected at any time, the licensee should stop using the irradiator, restrict access to the area housing the irradiator, immediately notify the RSO, and determine if a report to the agency is required.
 - The licensee should not attempt to repair or authorize others to attempt to repair the irradiator except as specifically authorized in a license issued by VDH.

Elements of Emergency Procedures Applicable to All types of Self-Shielded Irradiators

- Leave the irradiator area (to reduce radiation exposure).
- Control access to the area (e.g., lock door).
- Contact responsible individuals (e.g., names, phone numbers of RSO, irradiator manufacturer (or distributor), emergency response organizations such as fire department, agency).
- Take additional steps, dependent on the specific situations (e.g., surveys).
- As appropriate, require timely reporting to the agency

Changes to Operating and Emergency Procedures Without a License Amendment

Licensees may change their operating and emergency procedures without amending their license if:

- The changes are reviewed and approved by licensee management and the RSO
- Affected licensee staff are trained in the procedures before they are implemented
- The changes are consistent with applicable license conditions and the procedures or commitments submitted in the license application
- The changes do not degrade the safety of the program.

Copies of operating and emergency procedures should be provided to all users. Post a current copy at each irradiator's control panel. If posting the operating procedures is not practicable, post a notice describing the document(s) and where it may be examined.

Appendix P

Leak Test Program

Leak Test Program

Training

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

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

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

Appropriate on-the-job-training consists of:

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

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests will be analyzed in a low-background area.
- Individuals conducting leak tests will use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed. 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:

$$MDA = \frac{2.71 + 4.65\sqrt{B_R \times t}}{t \times E} = \text{Minimum Detectable Activity}$$

where:

MDA	=	activity level in disintegrations per minute
B_R	=	background rate in counts per minute
t	=	counting time in minutes
E	=	detector efficiency in counts per disintegrations

For example:

B_R	=	200 counts per minute
E	=	0.1 counts per disintegration (10% efficient)
t	=	2 minutes

$$MDA = \frac{2.71 + 4.65\sqrt{(200 \times 2)}}{2 \times 0.1} = \frac{2.71 + 4.65\sqrt{(400)}}{0.2}$$

$$= \frac{2.71 + 4.65(20)}{0.2} = \frac{2.71 + 93}{0.2} = \frac{95.71}{0.2}$$

$$= \frac{59 \text{ disintegrations}}{\text{minute}}$$

$$\text{becquerels (Bq)} = \frac{1 \text{ disintegration}}{\text{second}}$$

$$\text{Bq} = \frac{59 \text{ disintegrations}}{\text{minutes}} \times \frac{\text{minute}}{60 \text{ seconds}} = 0.98 = 1 \text{ Bq}$$

- A NaI(Tl) well counter system with a single or multi-channel analyzer will be used to count samples from irradiators containing gamma-emitters (e.g., Cs-137, Co-60).
- A liquid scintillation or gas-flow proportional counting system will be used to count samples from irradiators containing beta-emitters (e.g., Sr-90).

Frequency for Conducting Leak Tests of Sealed Sources

- Leak tests will be conducted at the frequency specified in the respective SSDR Certificate.

Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as self-shielded irradiator 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 microcurie) of the radionuclide in the irradiator.
- 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 $\pm 5\%$ of the stated value and traceable to primary radiation standards such as those maintained by NIST.
- Calculate efficiency.

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

Where:

cpm	=	counts per minute
std	=	standard
bkg	=	background
Bq	=	Becquerel

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

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

- Sign and date the list of sources, date 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 the agency.

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

Appendix Q

Transportation

Part 1: Major DOT Regulations

The major areas in the DOT regulations that are most relevant for transportation of typical self-shielded irradiators that are shipped as Type A or Type B quantities are as follows:

- Table of Hazardous Materials and Special Provisions **49 CFR 172.101**, and App. A, Table 2: Hazardous materials table, list of hazardous substances and reportable quantities
- Shipping Papers **49 CFR 172.200-204**: general entries, description, additional description requirements, shipper's certification
- Package Markings **49 CFR 172.300**, **49 CFR 172.301**, **49 CFR 172.303**, **49 CFR 172.304**, **49 CFR 172.310**, **49 CFR 172.324**: General marking requirements for non-bulk packagings, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging
- Package Labeling **49 CFR 172.400**, **49 CFR 172.401**, **49 CFR 172.403**, **49 CFR 172.406**, **49 CFR 172.407**, **49 CFR 172.436**, **49 CFR 172.438**, **49 CFR 172.440**: General labeling requirements, prohibited labeling, radioactive materials, placement of labels, specifications for radioactive labels
- Placarding of Vehicles **49 CFR 172.500**, **49 CFR 172.502**, **49 CFR 172.504**, **49 CFR 172.506**, **49 CFR 172.516**, **49 CFR 172.519**, **49 CFR 172.556**: Applicability, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, RADIOACTIVE placard
- Emergency Response Information, Subpart G, **49 CFR 172.600**, **49 CFR 172.602**, **49 CFR 172.604**: Applicability and general requirements, emergency response information, emergency response telephone number
- Training, Subpart H, **49 CFR 172.702**, **49 CFR 172.704**: Applicability and responsibility for training and testing, training requirements
- Radiation Protection Program for Shippers and Carriers, Subpart I, **49 CFR 172.800**, etc.
- Shippers - General Requirements for Shipments and Packaging, Subpart I, **49 CFR 173.403**, **49 CFR 173.410**, **49 CFR 173.411**, **49 CFR 173.412**, **49 CFR 173.413**, **49 CFR 173.415**, **49 CFR 173.416**, **49 CFR 173.433**, **49 CFR 173.435**, **49 CFR 173.441**, **49 CFR 173.471**, **49 CFR 173.475**, **49 CFR 173.476**: Definitions, general design requirements, industrial packages, additional design requirements for Type A packages, requirements for Type B packages, authorized Type A packages, authorized Type B packages (including package certification requirements), requirement for determining A_1 and A_2 ..., table of A_1 and A_2 values for radionuclides, radiation level limit, requirements for U.S. NRC-approved packages (Type B), quality control requirements prior to each shipment..., approval of special form radioactive materials
- Carriage by Public Highway, **49 CFR 177.816**, **49 CFR 177.817**, **49 CFR 177.834(a)**, **49 CFR 177.842**: Driver training, shipping paper, general requirements (secured against movement), Class 7 (radioactive) material.

Part 3: Irradiators Built Before 1966

Before the adoption of the requirements of **10 CFR Part 71** in 1966, irradiators could be transported without being evaluated under the hypothetical accident conditions now incorporated in **10 CFR Part 71**. Unlike most post-1966 irradiators, pre-1966 irradiations are not certified shipping packages. Transport of pre-1966 units may require transferring the sealed source from the irradiator to a Type B package or use of a certified package for the irradiator containing the sealed sources.

VDH will consider a licensee's request for an exemption for a one-time shipment from **12VAC5-481-3130** only if these options are not viable.

An exemption may be granted if the request is authorized by law and will not endanger life or property or the common defense and security. In this case, an exemption request should demonstrate the need for the exemption, describe why alternatives considered are not viable, specify from what requirement(s) an exemption is requested and the period for which the exemption is requested, and describe steps taken to ensure that the shipment will not endanger life or property or the common defense and security (e.g., steps to minimize accident risk and to respond to a transportation accident). Typically, approved requests are for a limited period (e.g., 30 days).

Circumstances vary, but additional information supporting an exemption request may include the following:

- Manufacturer's (or distributor's) name and model number of the irradiator, the type and activity of radioactive material to be transported, and brief description of proposed trip (starting and ending points and approximate distance)
- Engineering drawings of irradiator
- Consideration of the following:
 - DOT's hazardous material routing requirements
 - Transport during time of low road usage
 - Use of good roads and avoidance of residential areas to maximum extent possible
 - Accompaniment of shipment by escort knowledgeable in the use of radiation survey instruments
 - Provision of escort with appropriate survey instruments and supplies to permit the establishment of a radiation exclusion area
 - Written procedures to be followed by the escort in an emergency situation.
 - Use of exclusive-use vehicle and shoring to limit movement of package during transport
 - Notification of state radiological health officials and local fire department of time and route of shipment.
- Planned date of shipment

Before applying to VDH for its approval, the licensee should contact other states radiological organizations within each state through which the shipment will be made to confirm the points of contact and to discuss the proposed controls for the shipment.

VDH reserves the right to accompany a shipment of an irradiator.

The agency must review these requests, which are typically requests to amend materials (12VAC5-481 'Virginia Radiation Protection Regulations') licenses. Licensees should address their requests to:

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

In addition to a VDH exemption, the licensee may also need a DOT exemption; contact DOT's Office of Hazardous Materials Technology at 202-366-4545 for additional information.

The response from the licensee for the exemption must demonstrate that the request is authorized by law and will protect public health and safety. It must also include the following information:

- Establish that the irradiator was built before 1966.
- Explain why an approved package cannot be used, the alternatives considered, and why each is not viable.
- Specify from what requirement(s) an exemption is requested and the period for which the exemption is requested.
- Describe procedures, controls, and other actions to be taken to ensure that the shipment will not endanger life or property or the common defense and security.

Reference: The names, addresses, and telephone numbers for officials in Agreement and Non-Agreement States are available on the NRC's 'Federal and State Material and Environmental Management' web page at <http://www.nrc-stp.ornl.gov/>. As an alternative, contact VDH at (804) 864-8150, during office hours.

Hazard Communications for Class 7 (Radioactive) Materials

Labeling Packages (49 CFR 172.400-450)

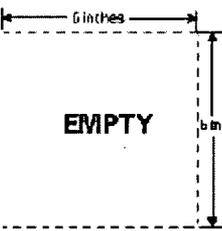
NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments. This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials.

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 (8) 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

<p>Size: Sides: > 100 mm (3.9 in.)</p> <p>Border: 5-8.3 mm (0.2-0.25 in.)</p>	 <p>49 CFR 172.436</p>	 <p>49 CFR 172.436</p>	 <p>49 CFR 172.440</p>	 <p>49 CFR 172.450</p>
Label	WHITE-I	YELLOW-II	YELLOW-III	EMPTY LABEL
Required when:	Surface radiation level < 0.005 Mew/hr (0.5 mem./hr)	0.005 Mew/hr (0.5 mem./hr) < surface radiation level ≤ 0.5 Mew/hr (50 mem./hr)	0.5 Mew/hr (50 mem./hr) < surface radiation level ≤ 2 Mew/hr (200 mem./h) [Note: 10 Mew/hr (1000 mem./hr) for exclusive-use closed vehicle (§173.441(b))]	The EMPTY label is required for shipments of empty Class 7 (radioactive) packages made pursuant to §173.428. It must cover any previous labels, or they must be removed or obliterated.
Or:	TI = 0 [1 meter dose rate < 0.0005 Mew/hr (0.05 mem./hr)]	TI < 1 [1 meter dose rate < 0.01 Mew/hr (1 mem./hr)]	TI < 10 [1 meter dose rate < 0.1 Mew/hr (10 mem./hr)] [Note: There is no package TI limit for exclusive-use]	
Notes:	<p>! Any package containing a Highway Route Controlled Quantity (HRCQ) must bear YELLOW-III label</p> <p>! Although radiation level transport indices (TIs) are shown above, for fissile material, the TI is typically determined on the basis of criticality control</p>			

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 4/1/87.
 - (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 exempted 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 (§ 172.432(c))

Commonwealth of Virginia
Radiation Protection Regulatory Guide



Guidance for 12VAC5-481
Part XII Irradiators

EPI-720 E

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

EXECUTIVE SUMMARY

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

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

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

This VAREG, ‘Guidance for **12VAC5-481 Part XII Irradiators**’ has been developed to streamline the application process for an **12VAC5-481 Part XII Irradiator License**. A copy of the VDH form, ‘Application for A Radioactive Material License Authorizing the Use of **12VAC5-481 Part XII Irradiators**’ is located in **Appendix A** of this guide.

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

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

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

- Use this regulatory guide to prepare the VDH form, 'Application for a Radioactive Material License Authorizing the Use of **12VAC5-481 Part XII Irradiators**' (**Appendix A**).
- Complete VDH Form, 'Application for a Radioactive Material License Authorizing the Use of **12VAC5-481 Part XII Irradiators**' (**Appendix A**). See 'Contents of Application' of the guide for additional information.
- Include any additional attachments.
 - All supplemental pages should be submitted on 8 ½" x 11" paper.
 - Please identify all attachments with the applicant's name and license number (if a renewal).
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original signed application along with attachments (if any).
- Submit the application fee (for new licenses only).
- Retain one copy of the license application and attachments (if any) for your future reference. You will need this information because the license will require that radioactive material be possessed and used in accordance with statements, representation, and procedures provided in the application and supporting documentation.

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

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ABBREVIATIONS

ACI	American Concrete Institute
ALARA	as low as is reasonably achievable
ALI	annual limit on intake
ANSI	American National Standards Institute
bkg	background
Bq	Becquerel
BPR	Business Process Redesign
BSR	Bulk Shielding Reactor
C	Celsius
CaF ₂	Calcium Fluoride
CFR	Code of Federal Regulations
C/Kg	Coulomb per Kilogram
Ci	Curie
cc	centimeter cubed
cm	centimeter
cm ²	centimeter squared
Co-60	Cobalt-60
cpm	counts per minute
Cs-137	Cesium-137
d	day
DOE	United States Department of Energy
DOT	United States Department of Transportation
dpm	disintegrations per minute
F	Fahrenheit
ft	foot
GM	Geiger-Mueller
GPO	Government Printing Office
hr	hour
IN	Information Notice
IP	Inspection Procedure
Kg	Kilogram
LiF	Lithium Fluoride
m	meter
MC	Manual Chapter
mCi	millicurie
min	minute
mR	milliroentgen
mrem	millirem
mSv	millisievert
MOU	Memorandum of Understanding
NaI (TI)	Sodium Iodide (Thallium-activated)
NCRP	National Council on Radiation Protection and Measurements
NFPA	National Fire Protection Association
NIST	National Institute of Standards and Technology
NLTNIF	National Low-Temperature Neutron Irradiation Facility
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program

OCFO	Office of the Chief Financial Officer
OCR	Optical Character Reader
OMB	Office of Management and Budget
ORNL	Oak Ridge National Laboratory
OSHA	Occupational Safety and Health Administration
OSL	optically stimulated luminescence dosimeters
OSP	Office of State Programs
P&GD	Policy and Guidance Directive
RG	Regulatory Guide
RQ	Reportable Quantities
RSO	Radiation Safety Officer
SI	International System of Units (abbreviated SI from the French Le Système Internationale d'Unites)
SSD	Sealed Source and Device
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
URL	Uniform Resource Locator
VDH	Virginia Department of Health, Radioactive Materials Program
wk	week
yr	year
μCi	microcurie
%	percent

PURPOSE OF GUIDE

This document provides guidance to an applicant in preparing a license application for a **12VAC5-481 Part XII Irradiators** license. It also provides guidance on VDH's criteria for evaluating a **12VAC5-481 Part XII Irradiator** license application. It is not intended to address the commercial aspects of manufacturing, distribution, and servicing of irradiators and their associated sources.

This guide addresses the variety of radiation safety issues associated with irradiators, of various designs, whose dose rates exceed 5 Gray (500 rads) per hour at one meter from the radioactive sealed sources in air or in water, as applicable to the irradiator's design. Because of differences in design, manufacturers provide appropriate written instructions and recommendations for proper operation and maintenance.

Table 1: Categories and Types of 12VAC5-481 Part XII Irradiators

Irradiator Type	Panoramic	Panoramic dry-source- storage	Panoramic wet-source- storage	Pool	Underwater
Sources stored in pool and removed to irradiate package/product	✓		✓	✓	
Sources stored in pool and package/product lowered into pool to be irradiated				✓	✓
Dry source storage and in-air irradiation of package/product	✓	✓			
Teletherapy unit converted to non-human use	✓	✓			

This guide describes the information needed to complete VDH Form, 'Application for a Radioactive Material License Authorizing the Use of 12VAC5-481 Part XII Irradiators' (Appendix A) for use of sealed sources in irradiators.

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

- **Rule** – references the requirements of 12VAC5-481 'Virginia Radiation Protection Regulations' applicable to the item;
- **Criteria** – outlines the criteria used to judge the adequacy of the applicant's response;
- **Discussion** – provides additional information on the topic sufficient to meet the needs of most readers; and
- **Response from Applicant** – shows the appropriate item on the application and provides: response(s), offers the option of an alternative response, or indicates that no response is needed on that topic.

The information submitted in the application must be sufficient to demonstrate that proposed equipment, facilities, personnel, and procedures are adequate to protect the health and safety of the citizens of the Commonwealth of Virginia in accordance with agency guidelines.

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

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

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

This VAREG provides the latest guidance and is modeled on the Nuclear Regulatory Commission’s (NRC) NUREG 1556, Volume 6. The VAREG shows the requirements in terms of **12VAC5-481** and provides a user-friendly format to assist with the preparation of a **12VAC5-481 Part XII** Irradiator license application.

LICENSES

Applicants should study this document, related guidance, and all applicable regulations carefully before completing the VDH form, 'Application for a Radioactive Material License Authorizing the Use of 12VAC5-481 Part XII Irradiators'. 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 2**). Applicants and licensees are responsible for finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. VDH recommends that applicants and licensees ask their local contacts for the federal agency controlling the site (e.g., contract officer, base environmental health officer, district office staff) to help determine the jurisdictional status of the land and to provide the information in writing, so that licensees can comply with VDH or NRC regulatory requirements, as appropriate. The following table lists examples of regulatory authority.

Table 2: Who Regulates Facilities in the Commonwealth of Virginia?

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

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

MANAGEMENT RESPONSIBILITY

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

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

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

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

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

APPLICABLE RULE

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

The following parts of **12VAC5-481** '**Virginia Radiation Protection Regulations**' contain requirements applicable to Irradiator licensees:

- Part I "General Provisions"
- Part III "Licensing of Radioactive Material"
- Part IV "Standards for Protection Against Radiation"
- Part X "Notices, Instructions and Reports to Workers; Inspections"
- Part XII "Licensing and Radiation Safety Requirements for Irradiators"
- 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 Authorizing the Use of 12VAC5-481 Part XII Irradiators' (**Appendix A**).
- For each separate sheet, other than submitted with the application, identify and key it to the item number on the application, or the topic to which it refers.
- Submit all documents on 8 ½ x 11 inch paper.
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original, signed application.
- Retain one copy of the license application for your future reference.

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

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

WHERE TO FILE

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

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

LICENSE FEES

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

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

Direct all questions about VDH's fees or completion of **Item 11** of VDH form, 'Application for a Radioactive Material License Authorizing the Use of **12VAC5-481 Part XII** Irradiators' (**Appendix A**) to: Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, Virginia 23219 or (804) 864-8150.

CONTENTS OF AN APPLICATION

Item 1: Type of Application

On the application, check the appropriate box and, if appropriate, note the license number.

Response from Applicant:

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

Item 2: Name and Mailing Address Of Applicant

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

Notify the agency of changes in mailing address.

Response from Applicant:

Item 2 Name And Mailing Address Of Applicant: Applicant's Telephone Number (Include area code): () - x
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Note: The agency must be notified in the event of change of ownership or control and bankruptcy proceedings, see below for details

Timely Notification of Transfer of Control

Rule: 12VAC5-481-330; 12VAC5-481-450; 12VAC5-481-500

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

Discussion: Transfer of control may be the result of mergers, buyouts, or majority stock transfers. Although it is not the agency's intent to interfere with the business decisions of

licensees, it is necessary for licensees to obtain prior agency written consent before the transaction is finalized. This is to ensure the following:

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

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

Notification of Bankruptcy Proceedings

Rule: 12VAC5-481-500 E & F

Criteria: Immediately following filing of voluntary or involuntary petition for bankruptcy, the licensee must notify VDH, in writing, identifying the bankruptcy court in which the petition was filed and the date of filing.

Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains totally responsible for all regulatory requirements. VDH needs to know when a licensee is in bankruptcy proceedings in order to ensure the material and facilities are under control, in accountability, and do not cause any public health and safety concerns. VDH shares its findings with other entities (i.e., trustees, etc) so that health and safety issues can be resolved prior to completion of bankruptcy proceedings.

Item 3: Person to Contact Regarding Application

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

Discussion: This is typically the proposed Radiation Safety Officer (RSO) or a knowledgeable management official, unless the applicant has named a different person as the contact. The agency will contact this individual if there are questions about the application.

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

Response from Applicant:

<p>Item 3 Person To Contact Regarding Application:</p>
<p>Contact's Telephone Number (Include area code): () - x</p>

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

Rule: 12VAC5-481-450; 12VAC5-481-500; 12VAC5-481-2680

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

Discussion: Specify the street address, city, and state or other descriptive address (e.g., on Highway 58, 5 miles east of the intersection of Highway 11 and State Route 16, Anytown, VA) for each facility. The descriptive address should be sufficient to allow a VDH inspector to find the facility location. A Post Office Box address is not acceptable.

A VDH license does not relieve a licensee from complying with other applicable federal, state, or local requirements (e.g., local zoning requirements or local ordinances requiring registration of radioactive material).

Response from Applicant:

Item 4 Address(es) Where Licensed 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

Note: As discussed later in the section 'Financial Assurance and Record Keeping for Decommissioning', licensees need to maintain permanent records on where licensed material was used or stored while the license was in force. This is important for making future determinations about the release of these

locations for unrestricted use (e.g., before the license is terminated). For irradiator licensees, acceptable records are sketches or written descriptions of the specific locations where licensed material was used or stored and any information relevant to leaking radioactive sources.

Item 5: Radiation Safety Officer (RSO)

Item 5.1: Radiation Safety Officer (RSO) Training and Experience

Rule: 12VAC5-481-450 A; 12VAC5-481-2680

Criteria: A Radiation Safety Officer (RSO) must have adequate training and experience. Successful completion of training as described in **Appendix G** is evidence of adequate training and experience.

Discussion: The person responsible for the radiation protection program is called the RSO. The application must include the name and a description of the training and experience of the proposed RSO. This is to determine whether the individual is qualified to function as the RSO. If the RSO has had neither previous formal training in health physics nor certification by the American Board of Health Physics, the RSO should complete a radiation safety course. Training should include approximately 40 hours covering the following topics:

- Radioactivity and radioactive decay
- Interactions of radiation with matter
- Biological effects of radiation
- Radiation detection using radiation detection instruments and personnel dosimeters
- Basic radiation protection principles and good safety practices (including time, distance, and shielding)
- Radiation protection regulations.

The course should include a written test or evaluation of the individual's comprehension of these topics.

In addition to the above general course, if the RSO was previously an RSO at a similar licensee or was trained as an irradiator operator but has not had experience working at an irradiator, he or she should have the equivalent of at least 40 hours in self-study or directed study on information directly applicable to radiation safety of irradiators. This should include applicable regulations (12VAC5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation' and Part XII 'Licensing and Radiation Safety Requirements for Irradiators') and reports or studies describing case histories of accidents or problems at irradiators; see **Appendix G**. The license application should list the documents studied or to be studied in the description of the training of the proposed RSO and should describe how the applicant will evaluate the individual's comprehension of the information studied.

The RSO should have at least 3 months (full-time equivalent) of experience at the applicant's irradiator or at another irradiator of a similar type. The 3 months of experience may include preoperational involvement, such as acceptance testing, while the irradiator is being constructed. However, to allow flexibility, the agency will determine the adequacy of the RSO's training and

experience on a case-by-case basis, looking at his or her actual qualifications and drawing on the VDH staff's experience in reviewing such qualifications.

Item 5.2: Radiation Safety Officer (RSO) Responsibilities and Authorities

Rule: 12VAC5-481-450 A; 12VAC5-481-2680

Criteria: RSOs must be in a position within the licensee's organization to have adequate authority over radiation safety activities and responsibility for regulatory compliance and protection of public health and safety.

Discussion: The RSO should have independent authority to stop operations that he or she considers unsafe and to conduct necessary tests or measurements. The RSO should be relatively independent of production responsibilities, to the extent practicable, considering the size of the staff at the facility. The RSO should report directly to the facility manager. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that licensed materials are used in a safe manner. Typical RSO duties are described in **Appendix H**. VDH requires the name of the RSO on the license to ensure that licensee management has always identified a responsible, qualified person and that the named individual knows of his or her designation as RSO.-

Describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the RSO and other management personnel who have important radiation safety responsibilities and authorities. In particular, the application should describe who has the authority to stop unsafe operations.

Response from Applicant:

Item 5. Radiation Safety Officer (RSO) (Check one box and attach evidence of training and experience)	
Name: _____	Telephone Number (Include area code): () - X _____
<input type="checkbox"/> Before obtaining radioactive material, the proposed RSO will have successfully completed training as described in Appendix G of VAREG 'Guidance for 12VAC5-481 Part XII Irradiators '. Before being named as the RSO, future RSOs will have successfully completed training as described in Appendix G of VAREG 'Guidance for 12VAC5-481 Part XII Irradiators '	
OR	
<input type="checkbox"/> Alternative information demonstrating that the proposed RSO is qualified by training and experience is attached. Before being named as the RSO, future RSOs will have successfully completed training as described in Appendix G of VAREG 'Guidance for 12VAC5-481 Part XII Irradiators '.	
AND	
<input type="checkbox"/> Description of organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities has been attached as required by 12VAC5-481-2680 .	

Note: It is important to notify the agency, as soon as possible, of changes in the designation of the

RSO. If the replacement is sudden, the licensee should contact the agency as soon as possible. While the amendment request is being reviewed by the agency, the proposed RSO may assume the responsibilities of RSO if the agency is given adequate information to ensure that the proposed individual will meet the required training.

Item 6: Irradiator Operators and Individuals Who Require Unescorted Access

Item 6.1: Initial Training and Experience For Irradiator Operators

Rule: 12VAC5-481-30; 12VAC5-481-450; 12VAC5-481-2260; 12VAC5-481-2270; 12VAC5-481-2280; 12VAC5-481-2680; 12VAC5-481-2730; 12VAC5-481-2830; 12VAC5-481-2840; 12VAC5-481-2900

Criteria: Irradiator operators must have adequate training and experience. Successful completion of one of the following is evidence of adequate training and experience:

- Irradiator manufacturer's course for operators specific to the irradiator that the applicant intends to use;

OR

- Training course as described in **Appendix G**.

The training provided to individuals to qualify them to be irradiator operators must include:

- Instruction
- On-the-job or simulator training (i.e., supervised experience)
- Means employed by the applicant to test each individual's understanding of VDH rules and licensing requirements and the irradiator operating and emergency procedures
- Minimum training and experience of personnel who may provide training.

In addition, instruction must be provided to at least one other individual who will be on site during operations on how to respond to the independent backup access control alarm and to promptly render or summon assistance.

Applicants requesting to perform non-routine operations such as loading and unloading sources must provide additional training. For more information see **Appendix I**.

Discussion: Irradiator operators have the responsibility to ensure the proper use and security of irradiators containing licensed material. Irradiator operators must receive training and instruction, and be tested before being permitted to operate an irradiator.

Training should be commensurate with the complexity of the irradiator design and potential radiation hazard (e.g., approximately 40 hours of instruction for pool-type panoramic irradiators and approximately 20 to 30 hours of instruction for underwater irradiators). Up to 50% of that instruction may be self-study or reading. The written test should cover the range of topics addressed in the instruction.

On-the-job training should be supervised by an experienced operator and should last at least 1 month full-time. If an approved operator does not operate the irradiator for more than a year, his or her performance during operation should:

- Be audited for at least 1 day before he or she is permitted to operate the irradiator independently; and
- Receive a safety review regarding the irradiator.

The requirements in **12VAC5-481-2830** are for an individual to become qualified initially as an irradiator operator. The safety reviews and evaluation requirements of **12VAC5-481-2830**, however, apply to all irradiator operators. Licensees should also conduct safety reviews at intervals not to exceed 12 months thereafter.

Individuals must be trained in the following subjects to become an irradiator operator:

- The fundamentals of radiation safety as they apply to irradiators
 - The goal is to provide the individual with the necessary foundation to perform his or her task safely and to help the individual worker understand the basis for the safety requirements and procedures that will be taught.
- The requirements of **12VAC5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation' and Part XII 'Licensing and Radiation Safety Requirements for Irradiators'**
 - The operator is not expected to be an expert on VDH regulations or to be able to determine whether a given procedure is adequate to meet VDH regulations. Instead, operators should be instructed on VDH requirements that are directly applicable to their responsibilities.
- The operation of the licensee's irradiator
 - The objective is to help the person understand the operating and emergency procedures, not to become an engineer.
- Licensee operating and emergency procedures that the individual will be required to perform
 - This is the most important part of the training because operating the irradiator safely depends on following these procedures correctly. The objective is that the operator correctly performs his or her assigned tasks. The training does not have to include procedures that the individual will not perform.
- Case histories of accidents and problems involving irradiators
 - The individual should be taught about situations that could lead to problems associated with irradiator operations. Instruction material on accidents is often difficult to obtain.

NUREG-1345, "Review of Events at Large Pool-Type Irradiators", provides some relevant information. Additional training is required for irradiator operators if they will perform non-routine operations. For more information see **Appendix I**.

Item 6.2: Annual Safety Reviews and Performance Evaluations for Irradiator Operators

Rule: 12VAC5-481-450; 12VAC5-481-630; 12VAC5-481-2270; 12VAC5-481-2830

Criteria: Licensees must conduct safety reviews for irradiator operators annually. Licensees must also evaluate the safety performance of each irradiator operator annually.

Discussion: Licensees must provide refresher training called a safety review to irradiator operators as well as evaluate the safety aspects of each irradiator operator's performance (i.e., performance evaluation).

Annual Safety Reviews

Safety reviews must include, as appropriate, each of the following areas:

- Changes in operating and emergency procedures since the last review
- Changes in VDH regulations and license conditions since the last review
- Reports on recent accidents, mistakes, or problems that have occurred at irradiator facilities
- Relevant results of inspections of operator safety performance
- Relevant results of the facility's inspection and maintenance checks
- A drill to practice an emergency or abnormal event procedure.

Also, each operator must be given a brief written test on the information covered during the safety review (12VAC5-481-2830).

The duration of safety reviews should be commensurate with the complexity of the irradiator's design and potential radiation hazard (e.g., approximately 4 hours for panoramic wet-source-storage irradiators and 2 hours for dry-source-storage and underwater irradiators). Safety reviews may be conducted at intervals not to exceed 12 months or throughout the calendar year on an as-necessary basis. The "drill" referenced in 12VAC5-481-2830 means actually going through a procedure using the actual equipment in as realistic a manner as practical. For example, for a drill on the response to a fire alarm it is not necessary that the alarm actually be enunciated if sounding the alarm would be disruptive. Operators may also correct errors as they occur rather than waiting until the drill is over. Each operator need not go through the drill, but may watch or critique as another operator does.

Annual Performance Evaluations

The safety performance of each irradiator operator must be evaluated and reviewed at least every twelve months to ensure that regulations, license conditions, and operating and emergency procedures are followed. In addition, the results of the evaluation must be discussed with each operator along with instructions on how to correct any mistakes or deficiencies observed.

Individuals (e.g., the RSO or senior operators) conducting these reviews must have adequate training and experience to conduct such evaluations.

Item 6.3: Training for Individuals Who Require Unescorted Access

Rule: 12VAC5-481-30; 12VAC5-481-450; 12VAC5-481-2270; 12VAC5-481-2280; 12VAC5-481-2830; 12VAC5-481-2840

Criteria: Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for irradiator operators and the RSO, must be instructed and tested in precautions to avoid radiation exposure, procedures listed in 12VAC5-481-2840 that they must perform or comply with, and their proper response to alarms.

Discussion: According to 12VAC5-481-2270, all individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) must receive appropriate instruction on radiation safety. However, in some facilities certain individuals other than irradiator operators may require unescorted access to the radiation room of an irradiator. The applicant should identify those individuals (e.g., individuals who perform inspection and maintenance checks) and train them according to 12VAC5-481-2830.

Training may include the subjects described in **Appendix G**. Individuals should be tested on procedures which require unescorted access to conduct. Tests may be given orally. Applicants must develop and implement a program for instructing and testing individuals requiring unescorted access.

The applicant's program for instructing and testing unescorted individuals (other than irradiator operators) will be examined during inspections, but should not be submitted in the license application.

Response from Applicant:

<p>Item 6 Irradiator Operators and Individuals who Require Unescorted Access (Check all that apply)</p> <p><input type="checkbox"/> Before using radioactive material, irradiator operators will have successfully completed the irradiator manufacturer's course for operators specific to the irradiator that the applicant intends to use</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> Before using radioactive material, irradiator operators have received training as described in Appendix G in VAREG 'Guidance for 12VAC5-481 Part XII Irradiators' and as required by 12VAC5-481-2830.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> The safety performance of each irradiator operator will be evaluated and reviewed at least every twelve months to ensure that regulations, license conditions, and operating and emergency procedures are followed as required by 12VAC5-481-2830.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Before entering the radiation room of an irradiator or area around the pool of an underwater irradiator, individuals who require unescorted access will be instructed and tested in precautions to avoid radiation exposure and their proper response to alarms. Training may include the subjects described in Appendix G in VAREG 'Guidance for 12VAC5-481 Part XII Irradiators.'</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> A description of the training and experience for proposed operators and individuals who require unescorted access is attached.</p>

Note: Alternative responses will be evaluated using the criteria listed above.

Reference: NUREG-1345, "Review of Events at Large Pool-Type Irradiators", dated March 1989.

Item 7: Radioactive Material

Item 7.1: Sealed Sources and Devices

Rule: 12VAC5-481-440; 12VAC5-481-450; 12VAC5-481-500; 12VAC5-481-740; 12VAC5-481-840; 12VAC5-481-850; 12VAC5-481-860; 12VAC5-481-880; 12VAC5-481-1151; 12VAC5-481-2680; 12VAC5-481-2720; 12VAC5-481-2810; 12VAC5-481-2870; 12VAC5-481-3750

Criteria: For each sealed source requested, applicants must identify the sealed source by radionuclide, manufacturer (or distributor), and model number. Applicants will be authorized to possess only those sealed sources specifically approved or registered by NRC or another Agreement State for use in the requested irradiator. Also, identify any depleted uranium that is used as shielding material (teletherapy units and other exposure devices may contain depleted uranium).

Discussion: 12VAC5-481-440 and 12VAC5-481-2720 list criteria for sealed sources used in irradiators. Normally, tests used to demonstrate that the criteria can be met are conducted by the source manufacturer (or distributor), not the applicant. The manufacturer (or distributor) then applies to the NRC or another Agreement State for approval for use in irradiators. The safety evaluation is documented in a Sealed Source and Device (SSD) Registration Certificate. Therefore, if sealed sources are approved for use in the requested irradiator by NRC or another Agreement State, the applicant need only note the manufacturer's (or distributor's) name and model number of the sources in its license application to demonstrate that the requirements are met.

Before the SSD registration process was formalized, some older sealed sources may not have been evaluated in this way, but were specifically approved on a license. Licensees can continue to use sealed sources that are specifically listed on their licenses. If a licensee wishes to install sealed sources that are not currently listed on the license, the new sources must meet the requirements of 12VAC5-481-2720.

Licensees may not make any changes to the sealed sources 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. A custom registration review may also be required. This would increase the time needed to process a licensing action.

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.

Item 7.2 Financial Assurance and Record Keeping for Decommissioning

Rule: 12VAC5-481-100; 12VAC5-481-450 C; 12VAC5-481-500; 12VAC5-481-510; 12VAC5-481-570; 12VAC5-481-571; 12VAC5-481-1161

Criteria: Irradiator licensees authorized to possess sealed sources containing radioactive material in excess of the limits specified in 12VAC5-481-450 C must provide evidence of financial assurance for decommissioning.

Even if no financial assurance is required, licensees are required to maintain, in an identified location, decommissioning records related to structures and equipment where licensed materials are used or stored and to leaking sources. Pursuant to 12VAC5-481-450 C 10 and 12VAC5-481-571 D, licensees must transfer these records important to decommissioning to either of the following:

- The new licensee before licensed activities are transferred or assigned in accordance with 12VAC5-481-500 B
- VDH before the license is terminated.

Discussion: The requirements for financial assurance are specific to the types and quantities of byproduct material authorized on a license. Most irradiator applicants and licensees need to take action to comply with the financial assurance requirements because their total inventory of licensed material exceeds the limits in 12VAC5-481-450 C.

NRC Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, contains approved wording for each of the mechanisms authorized by the regulation to guarantee or secure funds except for the Statement of Intent for VDH Licensees. See **Appendix E** for the recommended wording for a Statement of Intent.

All irradiator licensees must maintain records important to decommissioning, regardless of whether they need financial assurance for decommissioning. Licensees are required to maintain records important to decommissioning in an identified location (i.e., licensees must know the locations of all documents).

All irradiator licensees need to maintain records of structures and equipment for each irradiator. As-built drawings with modifications of structures and equipment shown as appropriate fulfill this requirement. If drawings are not available, licensees may substitute appropriate records (e.g., a sketch of the room or building or a narrative description of the area) concerning the specific areas and locations. In addition, if the applicant experiences unusual occurrences (e.g., leaking sources), they also need to maintain records about contamination that remains after cleanup or that may have spread to inaccessible areas. For irradiator licensees whose sources have never

leaked, sketches or written descriptions that include the location of each irradiator are considered acceptable records important to decommissioning.

Item 7.3: Purpose(s) For Which Licensed Material Will Be Used

Rule: 12VAC5-481-450; 12VAC5-481-2680; 12VAC5-481-2920

Criteria: The proposed purpose is authorized by the Atomic Energy Act of 1954, as amended. Sealed sources that are used in irradiators should be used only for the purposes for which they were designed, according to the manufacturer's written recommendations and instructions, as specified in an approved SSD Registration Certificate, and as authorized on VDH, NRC, or another Agreement State license.

Discussion: Requests to use sealed sources in irradiators for purposes not listed in the SSD Registration Certificate will be reviewed on a case-by-case basis. Examples might include greater than small quantities of flammable materials with a flash point below 60°C (140°F), irradiation of explosive material, or cryogenic material (under certain conditions particular irradiated cryogenic material can explode). If an applicant wants to irradiate greater than small quantities of flammable materials with a flash point below 60°C (140°F), see **Appendix F**. In addition, irradiation of explosives is generally prohibited; however, if an applicant wants to request irradiation of explosives, see **Appendix F**.

Applicants need to submit sufficient information to demonstrate that the proposed use will not compromise the integrity of the source or source shielding, or other radiation safety critical components of the device. The agency will evaluate the radiation safety program for each type and use of sealed sources in each irradiator requested.

Irradiation of food and certain other products intended for commercial distribution to the public are also subject to the regulations of the Food and Drug Administration (FDA) and U. S. Department of Agriculture (USDA). Contact these agencies for further information. A VDH licensee must also comply with applicable FDA or USDA regulations.

Note:

- Allowed uses of irradiators normally include the irradiation of food or products for human consumption or research purposes.
- Unusual uses will be evaluated on a case-by-case basis and the authorized use condition will reflect approved uses.

Response from Applicant:

Item 7 Radioactive Material (Attach additional pages if necessary)	
ELEMENT AND MASS NUMBER <input type="checkbox"/> Cobalt-60 <input type="checkbox"/> Strontium-90 <input type="checkbox"/> Cesium-37 <input type="checkbox"/> Other Isotope (please specify):	IRRADIATOR MANUFACTURER AND MODEL NUMBER
MAXIMUM QUANTITY (Not to exceed either the maximum activity per source or device as specified in the Sealed Source and Device Registration Certificate)	MAXIMUM AMOUNT OF DEPLETED URANIUM (KG)
SEALED SOURCE MANUFACTURER OR DISTRIBUTOR AND MODEL NUMBER	DEVICE MANUFACTURER OR DISTRIBUTOR AND MODEL NUMBER
MAXIMUM ACTIVITY PER SOURCE FOR DRY-SOURCE-STORAGE	INTENDED USE: (Specific description of use of each type of irradiator requested. A description of purposes and safety analysis to support safe use has been attached)
FINANCIAL ASSURANCE <input type="checkbox"/> We will submit the necessary documentation OR <input type="checkbox"/> N/A	

Note:

- For information on SSD registration certificates, contact the Registration Assistant by calling NRC's toll free number (800) 368-5642 and then asking for extension 415-7217.
- SSD reviews are not required for exposure devices in irradiators subject to **12VAC5-481 'Virginia Radiation Protection Regulations', Part XII 'Licensing and Radiation Safety Requirements for Irradiators'**. However, for some dry-source-storage panoramic irradiators (e.g., teletherapy units converted to non-human use), a review has been performed at the manufacturer's (or distributor's) request and this information may be useful in evaluating an application. If the irradiator has an exposure device for which a SSD review has been performed, the applicant should state that such a review has been performed and provide the registered name of the manufacturer (or distributor) and model number of the device.

Item 8: Facilities and Equipment

Item 8.1: Description of the Facility and Site

Rule: 12VAC5-481-450; 12VAC5-481-630; 12VAC5-481-740; 12VAC5-481-840; 12VAC5-481-1010, 12VAC5-481-2680; 12VAC5-481-2810; 12VAC5-481-2820, 12VAC5-481-2870

Criteria: Facilities and equipment must be adequate to protect public health and safety and to minimize danger to life or property. The application must include a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

Discussion: A diagram of the facility must be submitted for review with enough detail designating the location of required interlocks and radiation monitors to be used at the facility (e.g., blueprints with interlock and radiation monitor locations identified).

An applicant should provide a schedule for construction activities associated with the irradiator. This will allow the agency to inspect and ensure construction activities are according to design requirements as described in **12VAC5-481-2810**. Diagrams, drawings, sketches, or blueprints of facilities are needed for a clear understanding of the facility's design and its relationship to adjacent properties. Show locations of safety-related equipment and features as required in **12VAC5-481 'Virginia Radiation Protection Regulations', Part XII 'Licensing and Radiation Safety Requirements for Irradiators'**. Provide a construction schedule for the irradiator.

Minimization Of Contamination

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.

All applicants for new licenses need to consider the importance of designing and operating their facilities so as 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. Irradiator applicants usually do not need to address these issues as a separate item since they are included in responses to other items of the application.

Sealed sources and devices that are approved by VDH, NRC or another Agreement State and located and used according to their respective SSD Registration Certificates usually pose little risk of contamination. Leak tests performed as specified in **12VAC5-481-740** and **12VAC5-481-2870** should identify defective sources. Leaking sources must be withdrawn from use and decontaminated, repaired, or disposed of according to VDH requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts. Other efforts to minimize radioactive waste do not apply to programs using only sealed sources and devices that have not leaked.

Response from Applicant:

<p>Item 8.1 Description of the Facility and Site</p> <p><input type="checkbox"/> Diagrams of radioactive material area(s) are attached.</p> <p style="text-align: center;">AND EITHER</p> <p><input type="checkbox"/> We will ensure that each area where a irradiator is located corresponds to the 'Conditions of Normal Use' and 'Limitations and/or Other Considerations of Use' on the applicable irradiator's Sealed Source and Device Registration Certificate; the floor beneath the irradiator is secured to prevent unauthorized access or removal; and each area where a irradiator is located is equipped with an automatically operated fire detection and control system (sprinkler, chemical, or gas) or the location of the area and other controls ensure a low-level radiation risk attributable to fires.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will submit alternative information; which includes the justification for placing an irradiator in an area that does not correspond to the 'Conditions of Normal Use' and the 'Limitations and/or Other Considerations of Use.'</p>
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Item 8.2: Access Control

Rule: 12VAC5-481-450; 12VAC5-481-2680; 12VAC5-481-2730; 12VAC5-481-2770; 12VAC5-481-2810; 12VAC5-481-2820

Criteria: Irradiator facilities must have access controls to prevent inadvertent entry into the radiation room, as required by 12VAC5-481-2730.

Discussion: This section discusses two categories of irradiators:

- panoramic irradiators (dry-source-storage, wet-source storage)
- underwater irradiators.

Panoramic Irradiators

The door or barrier that serves as the primary access control system must have devices that will: 1) prevent the source from being moved out of its shielded position if the door or barrier were open; and 2) cause the source to return to its shielded position if the door or barrier were opened while the source was exposed.

Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open; opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The doors and barriers must not prevent any individual in the radiation room from leaving. The backup access control system must be able to detect entry while the source is exposed. If entry is detected, the system must: 1) automatically cause the source to return to its shielded position; and 2) activate audible and visible alarms.

Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to alert any individual entering the room to the hazard. The alarm must also alert at least one other individual who is onsite and prepared to render or summon assistance promptly.

A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted entry while the monitor measures high radiation levels must activate the alarm described in 12VAC5-481-2730. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam (e.g., an area of the maze that may expose the instrument directly to the irradiator sources when in the unshielded position).

The requirement in 12VAC5-481-2730 for a door or other physical barrier applies to each entrance of the radiation room, whether intended for personnel or product entrance or exit. A conveyor system could meet the requirement by providing a clearance large enough for a package, but too small for a person by using barriers that would require unusual exertion to

bypass. A photoelectric system cannot be considered a physical barrier. The purpose of this requirement is to prevent someone from carelessly or accidentally entering the radiation room while the sources are exposed.

This section also requires an independent backup access control system to provide a redundant means of preventing a person from being accidentally exposed to the source. In case of a failure of the interlocks on the door or barrier combined with a failure to follow operating procedures, the backup system should warn the person entering the radiation room of the danger and automatically cause the sources to return to their shielded position. The backup system could use photoelectric cells in an entrance maze, pressure mats on the floor, or similar means of detection.

The system must also alert another trained person who is onsite and prepared to render or summon assistance. The mechanism that moves the sources must require a key to actuate it. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any one time, and only irradiator operators or facility management may have access to it. The key must be attached to a calibrated portable radiation survey meter by a chain or cable. In addition, the lock for source control movement must be designed so that the key may not be removed if the sources are in an unshielded position. Also, the door to the radiation room must require the same key to open it. This redundant feature will ensure that the sources are in the shielded position prior to an individual entering the radiation room. It will also ensure that any individual entering the radiation room will have in his or her possession a calibrated portable radiation survey instrument for monitoring radiation levels in the radiation room in the event the sources were not in the shielded position.

Irradiators can produce ozone in concentrations exceeding those permitted by regulations of the Occupational Safety and Health Administration (OSHA) at **29 CFR 1910.1000**, "Air Contaminants." Nitrogen oxides can also be produced, although concentrations would not be expected to exceed OSHA limits. To control these gases, irradiators with large sources are typically equipped with ventilation systems to exhaust the gases before personnel entry. OSHA regulates exposure to ozone and other noxious gases in the workplace, and the U.S. Environmental Protection Agency regulates emissions offsite. If VDH personnel observe problems with noxious gases at an irradiator during an inspection, VDH will notify OSHA of the problem.

The radiation room must be equipped with a device integrated with the control system ensuring that the sources cannot be exposed unless the access door and other interlocks are engaged within a preset time of activating the control. The irradiator must be equipped with a safety timer that will automatically generate visible and audible warnings to alert personnel in the radiation room that the startup sequence has begun and provide sufficient time to leave the area or operate a clearly identified emergency stop device which will abort the startup sequence. The safety timer must be integrated with the control system so that the source cannot be exposed unless the startup sequence is complete within the preset time and the control console indicates that it is safe to expose the source.

For panoramic irradiators whose construction begins after July 1, 1993, the licensee must verify from the design and logic diagram that the access control system will meet the requirements of

12VAC5-481-2730. Before loading sources, the licensee must test the completed access control system to ensure that it functions as designed and that all alarms, controls, and interlocks work properly. For more information see **Appendix J**, "Construction Monitoring and Acceptance Testing."

Underwater Irradiators

The pool must be within an area surrounded by a personnel access barrier with an intrusion alarm when the facility is not operating. Only operators and facility management may have access to keys to the personnel access barrier. The intrusion alarm must be able to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual (not necessarily onsite) who is prepared to respond or summon assistance when the alarm is activated.

Response from Applicant:

Item 8.2 Access Control (check boxes)

For Underwater Irradiators we will submit specific information describing the access control system and how it works that demonstrates compliance with the requirements of **12VAC5-481-2730**. Specific drawings or sketches should be submitted, as appropriate.

OR

For Panoramic Irradiators, we will describe the facility alarm systems and describe the lock and key system for controlling source movement and discuss how it meets the requirements of **12VAC5-481-2770**.

Item 8.3: Shielding

Rule: 12VAC5-481-450; 12VAC5-481-2740; 12VAC5-481-2810; 12VAC5-481-2820

Criteria: Irradiator shielding must meet the requirements as described in **12VAC5-481-2740** and the requirements of local building codes or other appropriate sources.

Discussion: The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02 millisievert (mSv) (2 millirems (mrem)) per hour at any location 30 centimeters (cm) or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 cm. The maximum dose rate of 0.02 mSv (2 mrem) per hour is considered practical to achieve. Areas where the radiation dose rate exceeds 0.02 mSv (2 mrem) per hour must be locked, roped off, or posted. These may include areas not normally occupied such as the equipment access area on the roof of the irradiator.

The radiation dose at 30 cm over the edge of the pool of a pool irradiator may not exceed 0.02 mSv (2 mrem) per hour when the sources are in the fully shielded position. The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator when the source is

shielded may not exceed 0.02 mSv (2 mrem) per hour and at 30 cm from the shield may not exceed 0.2 mSv (20 mrems) per hour.

For panoramic irradiators:

- If not built in seismic areas, it is acceptable that shielding meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of **12VAC5-481-2740**.
- If built in seismic areas, the applicant must design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.
- ANSI Standard 43.10 (last issued 1984) paragraph 8.25 discusses geologic and seismic site considerations which should be evaluated prior to building a panoramic irradiator.
- The licensee must monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete. See **Appendix J**, "Construction Monitoring and Acceptance Testing."
- If the irradiator will use more than 2×10^{17} becquerels (Bq) (5 million curies) of activity, the applicant must evaluate the effects of heating of the shielding walls by the irradiator sources (e.g., thermal effects on concrete).

Response from Applicant:

<p>Item 8.3 Shielding (check boxes)</p> <p>For Panoramic Irradiators:</p> <p><input type="checkbox"/> We will describe the shielding to be used and its composition AND</p> <p><input type="checkbox"/> We will submit a diagram showing the configuration of shielding including walls and the ceiling and indicate the thickness of each and penetrations in the shielding AND</p> <p><input type="checkbox"/> If any accessible areas outside the shield are expected to have a dose rate exceeding 0.02 mSv (2 mrem) per hour, we will identify the areas and explain how access will be controlled AND</p> <p><input type="checkbox"/> For requests to possess more than 2×10^{17} Bq (5 million curies), we will submit an evaluation of the effects of heating of the shielding walls by the irradiator sources</p> <p>For Panoramic Irradiators whose construction will start after July 1, 1993</p> <p><input type="checkbox"/> We have identified the building code requirements to which shielding walls will be built and inspections of the construction that will be performed by local authorities so that they do not adversely impact the VDH requirements.</p> <p>For Underwater Irradiators, no response is required from the applicant in a license application.</p>
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Note: VDH does not approve irradiator shield designs. Instead, the agency conducts inspections to ensure that the maximum dose rate outside the completed shield is according to VDH requirements.

Reference: American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete." This standard is also available for purchase from the American Concrete Institute (ACI), P.O. Box 9094, Farmington Hills, Michigan 48333. ACI's telephone number is (248) 848-3700 and its URL is: <http://www.aci-int.org>.

Item 8.4: Fire Protection

Rule: 12VAC5-481-2750; 12VAC5-481-2810; 12VAC5-481-2820

Criteria: Panoramic irradiators must have smoke and heat detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded to meet the requirements as described in 12VAC5-481-2750 and 12VAC5-481-2810.

Discussion: The radiation room must have heat and smoke detectors that activate an audible alarm capable of alerting a person who can summon assistance promptly. The sources must become fully shielded automatically if a fire is detected.

The radiation room must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

The fire extinguishing system is required because a fire could disable the access control system or could prevent the sources from being shielded, thereby lowering the margin of safety. The fire extinguishing system must be operable without entry into the room. During a fire, there would be no means of assuring that the access control systems and source position indicators or the mechanism that returns the source to the shielded position had operated properly.

For panoramic irradiators whose construction starts after July 1, 1993:

- The applicant must verify that the number, location, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The applicant must verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and low characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.
- The licensee must test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. In addition, the licensee must test the operability of the fire extinguishing system. It is not required that licensees turn on extinguishers (i.e., water or chemicals) during tests of the operability of their fire protection systems. For more information see "Radiation Safety Program - Inspection and Maintenance Checks" and **Appendix J**, "Construction Monitoring and Acceptance Testing."

Response from Applicant:

Item 8.4 Fire Protection (Check boxes)

For Panoramic Irradiators, describe:

The type and location of the heat and smoke detectors to be used to detect a fire in the radiation room

AND

The alarms to alert personnel trained to summon assistance

AND

How the sources will automatically become fully shielded if a fire is detected

AND

How the heat and smoke detectors will be tested.

For Underwater Irradiators, no response is required, since the sources are always underwater and not subject to damage by fire.

Item 8.5: Radiation Monitors

Rule: 12VAC5-481-450 A; 12VAC5-481-2680; 12VAC5-481-2730; 12VAC5-481-2760; 12VAC5-481-2780; 12VAC5-481-2810; 12VAC5-481-2820; 12VAC5-481-2870

Criteria: Irradiator facilities must have radiation monitors to detect radiation levels and sources as described in 12VAC5-481 'Virginia Radiation Protection Regulations', Part XII, 'Licensing and Radiation Safety Requirements for Irradiators'.

Discussion: This section will only discuss the evaluation of the location of radiation monitors. For information regarding the calibration, sensitivity, and testing of monitors, see "Radiation Safety Program - Instruments."

For irradiators with automatic product conveyor systems:

The irradiator must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting a trained individual in the facility that is prepared to summon assistance.

For panoramic irradiators:

A monitor must be provided to detect the radiation level in the radiation room when the source is indicated to be in the fully shielded position. The monitor must be integrated with the personnel access door interlocks, as applicable, to prevent room access when the monitor detects an elevated radiation level for which the alarm set point is as low as practical but high enough to avoid false alarms. Room access must also be prevented if the monitor malfunctions or is turned off.

For underwater irradiators that are not in a shielded radiation room:

There must be a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly (e.g., prevent movement of irradiated product out of pool in the event water is contaminated).

For all irradiators whose construction begins after July 1, 1993:

- The licensee must ensure that the location and sensitivity of the monitor used to detect sources carried by the product conveyor system are appropriate.
- The licensee must verify that the product conveyor is designed to stop before a source on it could cause a radiation overexposure to any person.

For pool irradiators whose construction begins after July 1, 1993:

- If the licensee uses radiation monitors to detect contamination under 12VAC5-481-2870, the licensee must verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

Response from Applicant:

Item 8.5 Radiation Monitors (check boxes)

- We will describe the location and type of radiation monitors that will be used to meet the requirements of 12VAC5-481-2730, 12VAC5-481-2760 and 12VAC5-481-2870.
AND
- We will describe the location and types of alarms and those individuals who are trained to respond to those alarms. Diagrams and sketches should be used, as appropriate.
AND
- We will discuss the alarm set-points or the methods for establishing the alarm set-points.

For all Irradiators whose construction begins after July 1, 1993:

- We have verified the operability of radiation monitors and related alarms and interlocks prior to loading sources. For more information see Appendix J, "Construction Monitoring and Acceptance Testing."
AND
- We will describe the evaluation performed to meet 12VAC5-481-2810 on detector location and sensitivity and the acceptance testing that will be performed to meet 12VAC5-481-2820.

Note: All Underwater Irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of 12VAC5-481-2760.

Item 8.6: Irradiator Pools

Rule: 12VAC5-481-450 A; 12VAC5-481-2730; 12VAC5-481-2780; 12VAC5-481-2810; 12VAC5-481-2820

Criteria: Irradiator facilities with pools must be designed and equipped as described in 12VAC5-481 'Virginia Radiation Protection Regulations', Part XII, 'Licensing and Radiation Safety Requirements for Irradiators'.

Discussion: For facilities initially licensed after July 1, 1993, VDH requires either a water-tight stainless steel liner (or a liner metallurgically compatible with other components in the pool) or construction preventing substantial leakage and a pool surface designed to facilitate decontamination.

The purpose of the requirement is to reduce the likelihood of the pool leaking water that may be contaminated or used for shielding purposes. In either case, the licensee must have a method to store the sources safely during repairs of the irradiator pool.

For all licenses initially issued after July 1, 1993, irradiator pools must have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have breakers to prevent siphoning. Irradiator pools must have a means to replenish water that is lost. The means to replenish the water does not have to be automatic. Irradiator pools must also have a clearly visible indicator to show if the pool water level is above or below the normal low water level.

For all Pool Irradiators:

- A physical barrier, such as a railing or cover, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations. Also, this ensures compatibility with OSHA requirements and ANSI standards.
- Irradiator pools must be equipped with a purification system capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with enough clarity to allow for inspection of the source and source rack for damage and proper position. The water purification system is needed to minimize the probability of corrosion of the sealed sources and the source rack.
- The 0.02 mSv (2 mrem) per hour limit on the dose rates for poles and long-handled tools to be used in irradiator pools is imposed to prevent radiation streaming. Hollow and low-density poles and tools can have either vent holes to allow shielding water to enter or sufficient bends to prevent radiation levels at handling areas of the tools from exceeding 0.02 mSv (2 mrem) per hour.

For panoramic irradiators whose construction began after July 1, 1993, the licensee must verify that the pool design ensures its integrity as required by 12VAC5-481-2810 and that the design of the water purification system is adequate. The licensee must also conduct inspections and tests of the pool and water handling systems to meet the requirements of 12VAC5-481-2820. See **Appendix J**, "Construction Monitoring and Acceptance Testing."

Response from Applicant:

Item 8.6 Irradiator Pools (check boxes)

For all Pool Irradiators, describe:

- The high and low water-level indicators and their locations
AND
- The purification system for the pool with an explanation of why it is capable of maintaining pool water conductivity less than 20 microsiemens per centimeter
AND
- The means to replenish pool water
AND
- The barrier used during normal operation to prevent personnel from falling into the pool
AND
- How high radiation doses from radiation streaming will be avoided when using long-handled tools or poles (use sketches if appropriate).
AND
- If the pool has outlets more than 0.5 meter below the surface that could allow water to drain out of the pool, the means of preventing inadvertent excessive loss of pool water (in this context outlets do not include transfer tubes between adjacent pools because the transfer tubes do not provide a means to allow water to drain out of the pools).

For Irradiators licensed after July 1, 1993, describe:

- The pool liner. If no water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool is used, explain why the pool has a low likelihood of substantial leakage and how decontamination could be accomplished if necessary.

Item 8.7: Source Rack

Rule: 12VAC5-481-450 A; 12VAC5-481-2780; 12VAC5-481-2790; 12VAC5-481-2810; 12VAC5-481-2820

Criteria: Systems must be in place to protect the source rack.

Discussion: An important element in a radiation safety program is providing systems to protect the source rack and the mechanism that raises and lowers the sources.

For all irradiators, if the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

For irradiators whose construction begins after July 1, 1993:

- For pool irradiators, the licensee must verify that there are no crevices on the source or between the source and source rack that would promote corrosion on a critical area of the source (e.g., crevice corrosion, an inaccessible location in or around the sources or rack with low oxygen concentrations).

- For panoramic irradiators, the licensee must determine that if the source rack drops due to loss of power, the fall will not damage the source rack and that if the source rack drops due to failure of cables (or alternate means of support), it will not cause loss of integrity of sealed sources. In addition, licensees should review the potential of sealed sources to become dislodged from the source rack when dropped as a result of loss of power, failure of cables, or other alternate means of support.
- For panoramic irradiators, the licensee must review the design of the mechanism that moves the sources to ensure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.
- For panoramic irradiators, the licensee must test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power.
- For all irradiators with product conveyer systems, the licensee must observe and test the operation of the conveyer system to ensure that the requirements in **12VAC5-481-2790** are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.

See **Appendix J**, “Construction Monitoring and Acceptance Testing.”

Response from Applicant:

<p>Item 8.7 Source Rack (check boxes)</p> <p><input type="checkbox"/> We will submit procedures for ensuring source rack protection. If the product moves on a product conveyer system, describe the source rack protection to be provided to prevent products and product carriers from touching the source rack or mechanism that moves the rack.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> We will provide diagrams or sketches of those systems, if appropriate.</p>
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Item 8.8: Power Failures

Rule: 12VAC5-481-450 A; 12VAC5-481-2800; 12VAC5-481-2810; 12VAC5-481-2820

Criteria: If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources must automatically return to the shielded position. In addition, the lock on the door of the radiation room of a panoramic irradiator must not be deactivated by a power failure.

Discussion: Automatic source retraction in case of power loss must be accomplished without offsite power. The loss of offsite power may occur at irradiator facilities due to means outside the control of the licensee. In those cases where loss of offsite power occurs, the licensee is responsible for ensuring that the sources automatically return to the shielded position in accordance with **12VAC5-481-2800**. This is normally accomplished by an irradiator design that

does not need electrical energy to retract the sources. In addition, **12VAC5-481-2800** requires that the lock on the door of the radiation room may not be deactivated as the result of a power failure. It also requires that during a power failure, the licensee must ensure that anyone entering the area of any irradiator where sources are located must use an operable and calibrated radiation survey meter.

The licensee needs to demonstrate how the source rack would be retracted into the shielded position in the event of a power outage and what effects the loss of power would be on the lock of the door to the radiation room that contains the sources. If the locks on the doors did not function as designed and allowed entry into the radiation room, the licensee would need to have procedures in place to ensure that safety features would prevent an individual from being exposed to the sources if they did not retract to the shielded position. Backup power is not required as long as loss of power will cause the source to return to its shielded position (e.g., the source returns to the shielded position due to gravity).

For panoramic irradiators whose construction began after July 1, 1993, the licensee must test the ability of the source rack to return to its shielded position during a power loss greater than 10 seconds. For more information; see **Appendix J**, "Construction Monitoring and Acceptance Testing."

Response from Applicant:

Item 8.8 Power Failures (Check boxes)

For Panoramic Irradiators,

We will describe how loss of power will affect the lock on the doors in the radiation room.

AND

If construction began after July 1, 1993, we will describe how the sources are automatically returned to the shielded position if offsite power is lost for longer than 10 seconds.

For Underwater Irradiators, no response is required.

Reference: NRC Manual Chapter 2815 titled "Construction and Preoperational Inspection of Panoramic, Wet-Source-Storage Gamma Irradiators." This standard is also available for purchase from the American Concrete Institute (ACI), P. O. Box 9094, Farmington Hills, Michigan 48333. ACI's telephone number is (248) 848-3700 and its URL is <<http://www.aci-int.org>>.

Item 9: Radiation Safety Program

Item 9.1: Audit Program

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

Criteria: Licensees must review the content and implementation of their radiation protection programs at least every 12 months 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: Applicants must develop and implement an audit program. **Appendix K** contains a suggested audit program that is specific to the use of irradiators and is acceptable to the agency. All areas indicated in **Appendix K** may not be applicable to every licensee and all items may not need to be addressed during each audit. For example, licensees do not need to address areas which do not apply to their activities, and activities which have not occurred since the last audit need not be reviewed at the next audit.

Currently, the agency's emphasis in inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of irradiator operators to determine if, for example, operating and emergency procedures are available and are being followed.

It is essential that once identified, problems be corrected comprehensively and in a timely manner; 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 comprehensive correction of violations and deficiencies.

Licensees must maintain records of audits and other reviews of program content and implementation for 3 years from the date of the record. The agency has found audit records that contain the following information to be acceptable: date of audit, name of person(s) who conducted audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up.

Response from Applicant:

Item 9.1 Audit Program
 The applicant is not required to, and should not, submit its audit program to the agency for review. This matter will be examined during inspection.

Item 9.2: Radiation Monitoring Instruments

Rule: 12VAC5-481-450; 12VAC5-481-640; 12VAC5-481-720; 12VAC5-481-750; 12VAC5-481-1000; 12VAC5-481-2680; 12VAC5-481-2730; 12VAC5-481-2740; 12VAC5-481-2750; 12VAC5-481-2760; 12VAC5-481-2860; 12VAC5-481-2890; 12VAC5-481-2930

Criteria: VDH requires specific types of instruments to perform radiation surveys and to monitor certain activities.

Discussion: Irradiator licensees must have survey instruments and radiation monitors as described in **12VAC5-481-750** and **12VAC5-481-2760**. Irradiator licensees must have a variety of radiation detection instruments including portable survey instruments as well as fixed radiation monitors.

Survey Instruments

Surveys that are required before and during operation of all types of irradiators require using survey instruments which:

- measure the type of radiation expected
- are calibrated:
 - at least every 12 months
 - using a source of radiation similar to that found in the irradiator
 - after any servicing or repair (other than a simple battery exchange)
 - to ensure that exposure rates indicated by the meter do not vary from the actual exposure rates by more than $\pm 20\%$ on each scale
 - by the instrument manufacturer or person specifically authorized by the VDH, the NRC or another Agreement State to calibrate survey instruments
- do not saturate and read zero at high radiation dose rates.

The survey instruments should measure at least 0.05 mR through 200 mR per hour (2 mSv) and be checked for functionality with a source of radiation at the beginning of each day of use (e.g., with a check source). Plans to conduct non-routine operations such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the irradiator, sealed source relocation, replacement, and disposal of sealed sources, alignment or removal of sealed sources from service must include an evaluation of the type of survey instrument to be used because some of these operations may increase the individual's risk of radiation exposure. These operations should be carefully monitored with an appropriate survey meter. Furthermore, proper calibration of a survey meter is important for initial surveys since they can be used as a basis for public dose estimates. For those licensees requesting authorization to calibrate their own survey instruments, **Appendix L** contains calibration procedures acceptable to the agency.

Radiation Monitors

The requirements for use of radiation monitors are described in **12VAC5-481-2760** and shown in **Table 3**.

Fixed radiation monitors are used to detect the presence of radiation for various purposes at irradiator facilities. They are vital to access control systems because they provide electronic signals used to activate both audible and visual alarms when radiation is present. Monitors that warn individuals of the presence of high radiation or which are integrated with personnel access door locks to prevent room access under high radiation conditions should be designed to provide fail-safe operation (i.e., if the radiation monitor for any reason fails to respond to radiation, the system should provide for a backup warning system).

For radiation monitors, describe the type of monitors used to meet the requirements of 12VAC5-481-2730, 12VAC5-481-2760 and 12VAC5-481-2870. (The location of these monitors and alarm set-points were described in the response to “Facilities and Equipment - Radiation Monitors.”)

Table 3: Requirements for Radiation Monitors

Type of Irradiator	Monitor Required	Purpose of Monitor	Required Checks
Panoramic pool	Gamma sensing integrated with personnel access locks. Must activate alarm if entry is attempted while sensing radiation (12VAC5-481-2730)	Detects presence of high radiation in radiation room to prevent room access when radiation levels are high	Periodic checks with radioactive check source to confirm operability
All pool types (required unless water is checked daily by analysis of a sample of pool water)	Gamma sensing of pool circulating system. Must activate an alarm set-point as low as practical when pool is contaminated. (12VAC5-481-2870)	Detects a possible leaking sealed source	Periodic checks with radioactive check source to confirm operability and sensitivity.
Underwater type not in a shielded radiation room	Gamma sensing mounted over the pool. Must have an audible alarm capable of alerting an authorized individual. (12VAC5-481-2760)	Detects abnormal radiation levels	Periodic checks with radioactive check source to confirm operability and sensitivity
Any irradiator using a product conveyor system	Gamma sensing to detect and stop the product conveyor if a source is present (12VAC5-481-2760 and 12VAC5-481-2810)	Must stop conveyor before a source on the conveyor can cause a radiation overexposure to any person	Periodic checks with radioactive check source to confirm operability. The location and sensitivity of the monitor to detect sources carried by the product conveyor must be evaluated

Response from Applicant:

Item 9.2 Radiation Monitoring Instruments (Check one box)

We will use instruments that meet the radiation monitoring instrument specifications published in Appendix K of VAREG ‘Guidance for 12VAC5-481 Part XII Irradiators’. Additionally, each survey meter will have been calibrated by the manufacturer or other person authorized by VDH, the NRC, or another Agreement State to perform survey meter calibrations no more than 12 months before the date the meter is used.

OR

We will use instruments that meet the radiation monitoring instrument specifications published in Appendix K of VAREG ‘Guidance for 12VAC5-481 Part XII Irradiators’. Additionally, we will implement the model survey meter calibration program published in Appendix L of VAREG ‘Guidance for 12VAC5-481 Part XII Irradiators’ and we ensure that each survey meter will have been calibrated no more than 12 months before the date the meter is used.

OR

We will have access to survey equipment and/or procedures for ensuring that interlocks function, as required, to return moving irradiator sources to the shielded position and/or determining source shielding integrity after an incident involving the irradiator.

Notes:

- Alternative responses will be evaluated using the criteria listed above.
- The VDH license will state that survey meter calibrations will be performed by the instrument manufacturer or a person specifically authorized by VDH, NRC or another Agreement State to calibrate instruments, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey meter calibrations must submit additional information for review. See **Appendix L** for more information.
- Regardless of whether an applicant is authorized to calibrate survey meters or contracts an authorized firm to perform calibrations, the licensee must retain calibration records for at least 3 years.

Item 9.3: Material Receipt and Accountability

Rule: 12VAC5-481-100; 12VAC5-481-450; 12VAC5-481-500; 12VAC5-481-570; 12VAC5-481-571; 12VAC5-481-840; 12VAC5-481-850; 12VAC5-481-860; 12VAC5-481-900; 12VAC5-481-1000; 12VAC5-481-1090; 12VAC5-481-2680; 12VAC5-481-2730; 12VAC5-481-2750; 12VAC5-481-2840; 12VAC5-481-2930; 12VAC5-481-3100

Criteria: Licensees must do the following:

- Develop, maintain, and implement a procedure to account for licensed material.
- Maintain records of receipt, transfer, and disposal of licensed material (i.e., sealed sources).

Discussion: While loss, theft, or misplacement of licensed material at most irradiator facilities is unlikely because of limited access to sealed sources and the hazards involved with approaching unshielded sources, accountability for licensed materials must be ensured. Licensed materials must be tracked from 'cradle to grave' in order to ensure accountability and ensure that possession limits listed on the license are not exceeded.

Licensees must maintain records of receipt, transfer and disposal and implement an accountability procedure. Because this guide covers various types of irradiators, it is not possible to prescribe a specific procedure for material accountability that will apply to every situation. In developing a licensed material accountability program, the applicant should take into consideration the specific conditions at its facility. Receipt, transfer, and disposal records must be maintained for the times specified in 12VAC5-481-100, 12VAC5-481-570 and 12VAC5-481-2930.

Typically, these records contain the following types of information:

- Radionuclide, activity (in units of becquerels or curies), and date of measurement of byproduct material in each sealed source
- Manufacturer's (or distributor's) name, model number, and serial number of each sealed source containing byproduct material
- Location of each sealed source
- 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).

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

Response from Applicant:

Item 9.3 Material Receipt And Accountability (Check box)

We will submit a description of procedure(s) for ensuring material accountability.

Item 9.4: Occupational Dose

Rule: 12VAC5-481-630; 12VAC5-481-640; 12VAC5-481-650; 12VAC5-481-680; 12VAC5-481-690; 12VAC5-481-700; 12VAC5-481-710; 12VAC5-481-750; 12VAC5-481-760; 12VAC5-481-990; 12VAC5-481-1020; 12VAC5-481-1030; 12VAC5-481-1040; 12VAC5-481-2850

Criteria: The requirements for occupational dosimetry are shown in **Table 4**.

Table 4: Occupational Dose Limits For Adults

Occupational Dose Limits for Adults (12VAC5-481-640)	
<u>Body Location</u>	<u>Dose (Annual)</u>
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	

* The licensee must 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% of the allowable limits.

Discussion: Other individuals who perform certain non-routine operations (e.g., source loading, unloading, and repositioning; troubleshooting the control console; clearing stuck source racks; investigating/remediating removable contamination/leaking sources; (re)installing source cables; and any other activity during which personnel could receive radiation doses exceeding VDH limits) are likely to exceed 10% of the limits (see **Appendix I**). Applicants will also be required to provide dosimetry (whole body and perhaps extremity monitors) to individuals performing such services.

When personnel monitoring is needed, most licensees use either film badges, TLDs or optically stimulated luminescence dosimeters (OSL) that are supplied by a NVLAP-approved processor.

The exchange frequency for film badges is usually monthly due to technical concerns about film fading. The exchange frequency for OSL is usually quarterly. Applicants should verify that the processor is NVLAP-approved. Consult the NVLAP-approved processor for its recommendations for exchange frequency and proper use.

Some workers (e.g., package handlers, shipping personnel, and custodial personnel) may work near the irradiator but are not likely to exceed 10% of the limits. Refer to **Appendix M** for guidance for demonstrating that an unmonitored individual will not exceed 10% of the limits.

Response from Applicant:

<p>Item 9.4 Occupational Dose (Check one box)</p> <p><input type="checkbox"/> 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 and in accordance with 12VAC5-481-2850.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged at a frequency recommended by the processor.</p>

Item 9.5: Public Dose

Rule: 12VAC5-481-10; 12VAC5-481-630; 12VAC5-481-720; 12VAC5-481-730; 12VAC5-481-840; 12VAC5-481-1050; 12VAC5-481-2730; 12VAC5-481-2740; 12VAC5-481-2980; 12VAC5-481-3080

Criteria: Licensees must do the following:

- Ensure that irradiators and their sealed sources will be used, transported, and stored in such a way that individual members of the public will not receive more than 1 millisievert (mSv) [100 millirem (mrem)] in one year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour, from licensed operations.
- Control and maintain constant surveillance over licensed material that is not in storage and secure stored licensed material from unauthorized access, removal, or use.

Discussion: Members of the public include all persons who are not radiation workers. This includes persons who work or may be near locations where licensed material is used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where licensed material is used or stored.

Security procedures described in “Facilities and Equipment - Access Control,” states irradiator facilities must have access controls to prevent inadvertent entry into the radiation room, as required by **12VAC5-481-2730**, and should be sufficient to limit the exposure to the public during use or storage. Public dose is controlled, in part, by ensuring that irradiators are secure (e.g., irradiator is locked or located in a locked area) to prevent unauthorized access or use. Irradiator use is usually restricted by controlling access to the keys needed to operate the

irradiator and/or to keys to the locked irradiator area. Only authorized users should have access to these keys.

Public dose is also affected by the choice of storage and use locations and conditions. Since an irradiator produces a radiation field, it must be located and constructed so that the dose in an unrestricted area (e.g., an office or the exterior surface of an outside wall) does not exceed 0.02 mSv (2 mrem) in any one hour and the dose to an individual does not exceed 1 mSv (100 mrem) in a year. Use the concepts of time, distance, and shielding when choosing storage and use locations. Decreasing the time spent near an irradiator, increasing the distance from the irradiator, and using shielding (i.e., brick, concrete, lead, or other solid walls) will reduce the radiation exposure. Licensees must determine the radiation levels in unrestricted areas that are normally occupied during operation of an irradiator.

Table 5: Radiation Dose Limits Specified in 12VAC5-481-2740

Irradiator Type	Limit	Where Measured	Source Position
Panoramic	0.02 mSv (2 mrem) per hour	30 centimeters or more from the wall (of the room where the sources are exposed) in areas normally occupied	Exposed
Pool irradiator (including panoramic pool irradiators and underwater irradiators)	0.02 mSv (2 mrem) per hour	30 centimeters over the edge of the pool irradiator	Shielded
Dry-source-storage panoramic irradiator	0.02 mSv (2 mrem) per hour	1 meter from the shield of a dry-source-storage panoramic irradiator	Shielded
Dry-source-storage panoramic irradiator	0.2 mSv (20 mrem) per hour	5 centimeters from the shield	Shielded

Doses adjacent to the irradiator location can be determined by direct measurements and calculations using the “inverse square” law to evaluate the effect of distance on radiation levels, and occupancy factor to account for the actual presence of the member of the public. If, after making an initial evaluation, a licensee changes the conditions used for the evaluation (e.g., changes the shielding of the irradiator, increases the source strength, changes the type or frequency of irradiator use, or changes the occupancy of adjacent areas), then the licensee must perform a new evaluation to ensure that the public dose limits are not exceeded and take corrective action, as needed.

During agency inspections, licensees must be able to provide documentation demonstrating, by measurement or a combination of measurement and calculation, that the total effective dose

equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public. See **Appendix N** for examples of methods to demonstrate compliance.

Response from Applicant:

Item 9.5 Public Dose

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

Item 9.6: Operating and Emergency Procedures

Item 9.6.1: Operating Procedures

Rule: 12VAC5-481-630; 12VAC5-481-720; 12VAC5-481-840; 12VAC5-481-2260; 12VAC5-481-2680; 12VAC5-481-2730; 12VAC5-481-2770; 12VAC5-481-2840; 12VAC5-481-2880

Criteria: The applicant must have and follow written operating procedures for items specified in 12VAC5-481-2840.

Discussion: Operating procedures must be developed, maintained, and implemented to ensure that irradiators are used only as they were designed to be used, and radiation doses received by occupational workers and members of the public are ALARA. Copies of operating procedures should be provided to all irradiator operators. In addition, the applicant must post current copies of operating procedures applicable to licensed activities at each site. If posting of procedures is not practicable, the licensee may post a notice which describes the documents and states where they may be examined.

Improper operation could lead to the damage or malfunction of an irradiator and potentially lethal radiation overexposures to individuals. The applicant will provide summaries of the written operating procedures describing their important radiation safety aspects. The level of detail should be sufficient to demonstrate that regulatory requirements have been addressed.

If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

Normally, the manufacturer or a person specifically authorized by VDH, NRC or another Agreement State will perform non-routine operations involving, source loading, unloading and repositioning; troubleshooting the control console; clearing stuck source racks; investigating/remediating removable contamination/leaking sources; (re)installing source cables; and other critical operations requiring special skills or the potential for radiation overexposures. If these operations are not performed properly with attention to good radiation safety principles, the irradiator may not operate as designed and personnel performing the operations could receive

potentially lethal exposures. If the applicant wishes to perform non-routine operations, the information in **Appendix I** should be provided.

Repair and Preventive Maintenance

Outlines of maintenance, service, and repair procedures are not required. However, these should be done according to the manufacturer's written instructions, where applicable, by qualified personnel using their knowledge, experience, judgment, and skills to respond to each particular situation.

Improper repairs or maintenance not being performed in a timely fashion was identified as a contributing cause of many of the incidents reviewed in NUREG-1345, "Review of Events at Large Pool-Type Irradiators." Therefore, malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay. It is understood that it may be necessary to obtain a special part, piece of equipment, or particular skilled labor that may not be readily available. Licensees are allowed some flexibility in making non-critical repairs. As long as a reasonable effort is made, the licensee will meet the intent of the requirement. However, some repairs are critical and not subject to the latitude in **12VAC5-481-2880**. For example, licensees must make repairs to the access control system before operating the irradiator to ensure compliance with **12VAC5-481-2730**.

Preventive maintenance should be performed according to the manufacturer's written instructions. If manufacturer's written instructions are not available, the applicant should perform a review of the systems comprising the irradiator in consultation with knowledgeable individuals and determine and implement an appropriate schedule for preventive maintenance.

Security of Licensed Material

The agency considers security of licensed material extremely important and lack of security is a significant violation for which licensees may be subject to enforcement action. Although it is generally difficult to access sealed sources used in most irradiators, the applicant should develop, maintain, and implement procedures to prevent unauthorized access, removal, or use of the licensed material. Also, procedures should require that all areas associated with irradiator operations, particularly control and interlock systems, be locked and secured against unauthorized access.

Revision of Procedures

The licensee may revise operating procedures without VDH approval only if all of the following conditions are met:

- The revisions do not reduce the safety of the facility
- The revisions are consistent with the outline or summary of procedures submitted with the license application
- The revisions have been reviewed and approved by the RSO
- The users or operators are instructed and tested on the revised procedures before they are put into use.

Procedure for Identifying and Reporting Defects and Non--Compliance as Required by 10 CFR Part 21

Rule: 12VAC5-481-1100; 12VAC5-481-1110; 12VAC5-481-2940; 10 CFR Part 21

Criteria: Licensees must notify VDH if defects and failures are found in a basic component that could create a substantial safety hazard.

Discussion: Equipment defects that could create a substantial safety hazard or equipment failures involving VDH-regulated activities must be reported to VDH. For example, a failure of an access control system such that a person could enter the radiation room during a time when the sources are exposed in a panoramic irradiator or a defect in an interlock that prevents the operation of a panoramic irradiator in the event a roof plug or other movable shielding is not in place. Operating personnel should be instructed to report any malfunction or defect in irradiator equipment to management so that management can take appropriate action.

Item 9.6.2: Emergency Procedures

Rule: 12VAC5-481-630; 12VAC5-481-720; 12VAC5-481-740; 12VAC5-481-840; 12VAC5-481-1090; 12VAC5-481-1100; 12VAC5-481-1110; 12VAC5-481-1150; 12VAC5-481-2260; 12VAC5-481-2680; 12VAC5-481-2760; 12VAC5-481-2800; 12VAC5-481-2840; 12VAC5-481-2870; 12VAC5-481-2910; 12VAC5-481-2940; 10 CFR 21.21

Criteria: The licensee must have and follow emergency or abnormal event procedures, appropriate for items listed in 12VAC5-481-2840. Emergency procedures should include notifying the agency during and after emergencies and abnormal events.

Discussion: Licensees must have and follow emergency or abnormal event procedures, appropriate to the irradiator type, for:

- Sources stuck in the unshielded position
- Personnel overexposures
- A radiation alarm from the product exit portal monitor or pool monitor
- Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water (include 12VAC5-481-740 and 12VAC5-481-2870 requirements)
- A low- or high-water level indicator, an abnormal water loss, or leakage from the source storage pool
- A prolonged loss of electrical power (include 12VAC5-481-2800 and 12VAC5-481-2910 requirements)
- A fire alarm or explosion in the radiation room
- An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area
- Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility
- The jamming of automatic conveyor systems.

The applicant should consider other events which may require emergency or abnormal event procedures (e.g., abnormally high radiation levels indicated by the area radiation monitor, collision with the source(s) or source rack).

Emergency and abnormal event procedures should include who will be notified of the event, the role of the RSO, and what records of the event will be kept. The procedures should clearly identify telephone numbers of the RSO or other individuals who can provide assistance including the irradiator manufacturer (or distributor) and state and local agencies. The procedures should include actions to be taken immediately after discovering the emergency or abnormal event.

Emergency procedures should also include notifying the agency when events specified in **Appendix O** occur.

The RSO must be proactive in evaluating whether agency notification is required. Refer to **Appendix O** and the regulations (**12VAC5-481-1090**, **12VAC5-481-1100**, **12VAC5-481-1110**, **12VAC5-481-1150** and **12VAC5-481-2940**) for descriptions of when and where notifications are required.

Emergency procedures generally should not include post-emergency corrective actions and repairs, since there will be time to carefully consider such actions on a case-by-case basis after the situation is under control. Copies of emergency procedures should be provided to all irradiator operators. In addition, licensees must post current copies of emergency procedures applicable to licensed activities at each site. If posting of procedures is not practicable, the licensee may post a notice that describes the documents and states where they may be examined.

Emergency procedures for personnel overexposures, fire alarms, explosion in the radiation room, and natural phenomena may involve emergency responders outside the applicant's organization. The applicant should inform and/or train individuals in these organizations regarding the unique concerns and hazards associated with emergencies at the irradiator facility. For instance, hospitals should be informed about the different radiation accidents that could occur at the facility (i.e., overexposure vs. personnel contamination incident).

The licensee may revise emergency procedures without VDH approval only if all of the following conditions are met:

- The revisions do not reduce the safety of the facility
- The revisions are consistent with the outline or summary of procedures submitted with the license application
- The revisions have been reviewed and approved by the RSO
- The users or operators are instructed and tested on the revised procedures before they are put into use.

Provide an outline that specifically states the radiation safety aspects of the written emergency procedures listed in the "Discussion" section (i.e., those procedures listed in **12VAC5-481-2840**).

Response from Applicant:

Item 9.6 Operating And Emergency Procedures (Check all that apply)

- We will develop, implement, maintain, and distribute operating and emergency procedures that will meet the Criteria in the section titled 'Operating and Emergency Procedures' in VAREG 'Guidance 12VAC5-481 Part XII Irradiators'. (Procedures are attached)
- OR
- We will submit alternative procedures. (Procedures are attached)
- AND
- Licensees must have and follow emergency or abnormal event procedures, appropriate for the irradiator type as required by 12VAC5-481-2840.
- AND
- For routine operations: We will provide an outline that specifically states the radiation safety aspects of the written operating procedures (i.e., those procedures listed in 12VAC5-481-2840).

Note: Information requested in **Appendix I** will be reviewed on a case-by-case basis; if approved, the license will contain a condition authorizing the licensee to perform non-routine operations.

Reference: NUREG-1345, "Review of Events at Large Pool-Type Irradiators," dated March 1989 or IN 83-09: "Safety and Security of Irradiators," dated March 9, 1983.

Item 9.7: Leak Tests

Rule: 12VAC5-481-740; 12VAC5-481-1010; 12VAC5-481-1150; 12VAC5-481-2720; 12VAC5-481-2870; 12VAC5-481-2930; 12VAC5-481-2940; 12VAC5-481-3690

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

Discussion:

Dry-Source-Storage Sealed Sources

Each dry-source-storage sealed source must be tested for leakage at 6-month intervals. 12VAC5-481-2870 prohibits sources from being used unless the licensee tests the sources for leaks or has a certificate from a transferor that leak tests have been performed within 6 months before the transfer.

The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 200 becquerels (0.005 microcurie) of radioactivity and must be performed by a person approved by VDH, NRC, or another Agreement State to perform the test.

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

accumulate if the sealed source were leaking. Licensees may also be authorized to conduct the entire leak test sequence themselves. **Appendix P** contains a model leak test program.

Pool Irradiators

For pool irradiators, **12VAC5-481-2870** prohibits sources from being put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak tests have been performed within 6 months before the transfer. After placing sources in the pool, the water must be checked for contamination each day the irradiator operates. For pool irradiators, leak testing sources by wipe-testing is not highly sensitive or effective. The check may be done either by using a radiation monitor on a pool water circulating system or by analyzing a sample of pool water. If analyzing a sample of pool water, the results must be available within 24 hours.

Whether the applicant desires to check for contamination by analyzing a pool water sample daily, or by continuous monitoring, the procedures and sensitivity of the equipment to be used should be detailed in the application. If collecting a pool sample, use a sensitive detector, such as a sodium iodide detector, to verify the absence of detectable contamination in the sample. If using the continuous monitoring method, applicants may use a less sensitive detector such as a GM detector affixed to a filter/demineralizer where radioactive material would be concentrated.

If the licensee detects a leaking source, the licensee must promptly check personnel, equipment, facilities, and irradiated products for contamination. If any personnel or product are found to be contaminated, decontamination must be performed immediately. If a source is found to be leaking, the licensee must arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by a VDH, NRC, or another Agreement State licensee that is authorized to perform these functions. If the pool is contaminated, the licensee must arrange to clean the pool until the concentration levels do not exceed the appropriate concentration in **12VAC5-481-3690**. See **12VAC5-481-1100** and **12VAC5-481-1150** for reporting requirements. Upon detection of leaking sources, licensees should consider immediately stopping irradiator operations to minimize spread of contamination.

Response from the Applicant:

Item 9.7 Leak Tests (Check one box for each type)

For Dry-Source-Storage Irradiators:

Leak tests will be performed at intervals not to exceed 6 months and will be performed by an organization authorized by VDH, NRC, or another Agreement State to either perform the entire leak test sequence for other licensees or provide leak test kits to dry-source-storage licensee as required by **12VAC5 481-2870**.

OR

We will perform leak testing and sample analysis and will follow the model procedures in Appendix P of VAREG 'Guidance for **12VAC5-481 Part XII Irradiators**'. (Procedures are attached)

OR

We will submit alternative procedures. (Procedures are attached)

For Pool Irradiators:

We will include a description of equipment, procedures, and sensitivity of method that will be used to check for contamination by analysis of a sample of pool water.

OR

We will include a description of equipment, procedures, and sensitivity of method that will be used to check for contamination by continuous monitoring.

Note: Requests for authorization to perform leak testing and sample analysis will be reviewed and, if approved, VDH staff will authorize via a license condition.

References: Draft Regulatory Guide FC 412-4, "Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services," dated June 1985.

Item 9.8: Inspection and Maintenance Checks

Rule: 12VAC5-481-630; 12VAC5-481-2680; 12VAC5-481-2730; 12VAC5-481-2750; 12VAC5-481-2760; 12VAC5-481-2770; 12VAC5-481-2780; 12VAC5-481-2790; 12VAC5-481-2840; 12VAC5-481-2870; 12VAC5-481-2880; 12VAC5-481-2890

Criteria: The applicant must have and follow written procedures for inspection and maintenance checks for items specified in 12VAC5-481-2880.

Discussion: Applicants must periodically make inspection and maintenance checks to ensure proper operation of the irradiator. The applicant must have and follow procedures for inspection and maintenance checks. The frequency of checks is not stated in the regulations because it will be site-specific depending on the design of the facility. However, the frequency of checks must be specified in the application. In the applicant's description of the procedures, specify the frequency of the following items:

- Operability of each aspect of the access control system required by 12VAC5-481-2730
- Functioning of the source position indicator as required by 12VAC5-481-2770
- Operability of the radiation monitor for radioactive contamination in pool water required by 12VAC5-481-2870, using a radiation check source, if applicable
- Operability of the over-pool radiation monitor at underwater irradiators as required by 12VAC5-481-2760
- Operability of the product exit monitor required by 12VAC5-481-2760
- Operability of the emergency source return control required by 12VAC5-481-2770
- Leak-tightness of systems through which pool water circulates (visual inspection)
- Operability of the heat and smoke detectors and extinguisher system required by 12VAC5-481-2750 (but without turning extinguishers on)
- Operability of the means of pool water replenishment required by 12VAC5-481-2780
- Operability of the indicators of high and low pool-water levels required by 12VAC5-481-2780
- Operability of the intrusion alarm required by 12VAC5-481-2730, if applicable
- Functioning and wear of the system, mechanisms, and cables used to raise and lower sources
- Condition of the barrier to prevent products from hitting the sources or source mechanism as required by 12VAC5-481-2790
- Amount of water added to the pool to determine whether the pool is leaking.
- Electrical wiring on required safety systems for radiation damage
- Pool water conductivity measurements as required by 12VAC5-481-2890

The applicant should keep in mind that these are the minimum items to be checked based on requirements in 12VAC5-481-2880, and that the licensee should develop and implement procedures for other necessary checks as appropriate (e.g., as recommended by the

manufacturer). For instance, if applicable, the applicant should have and follow written procedures for inspection and maintenance checks to ensure that all product positioning system components, product boxes, or carriers continue to meet design specification and are not likely to cause an irradiator malfunction.

Response from Applicant:

Item 9.8 Inspection and Maintenance Checks (Check one box)

We will implement and maintain procedures for routine inspection and maintenance checks of our irradiators according to each manufacturer's (or distributor's) written recommendations and instructions. We will attach a description of inspection and maintenance checks, including the frequency of the checks as required by **12VAC5-481-2880**.

OR

Alternative procedures are attached.

Item 9.9: Transportation

Rule: 12VAC5-481-100; 12VAC5-481-570; 12VAC5-481-630; 12VAC5-481-2930; 12VAC5-481-2970; 12VAC5-481-2980; 12VAC5-481-3000, 12VAC5-481-3130; 49 CFR Parts 171-178

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

Discussion: The general license in **12VAC5-481-2970** provides the authorization used by most licensees to transport, or offer for transport, packages of radioactive material and specifies certain conditions. Transporting licensed materials originating at irradiator facilities normally involves quantities of radioactive material that require a Type B package. Because of the special requirements involved in shipping Type B packages, most irradiator licensees have chosen to transfer possession of radioactive materials to an irradiator manufacturer (or service licensee) with a VDH, NRC, or another Agreement State license who then acts as the shipper. The manufacturer (or service licensee), who is subject to the provisions of **12VAC5-481-2970**, as appropriate, then becomes responsible for proper packaging of the radioactive materials and compliance with VDH and DOT regulations. Licensees who do this must ensure that the manufacturer (or service licensee):

- Is authorized to possess the licensed material at temporary job sites (i.e., at the irradiator location)
- Actually takes possession of the licensed material under its license
- Uses an approved Type B package
- Is registered with VDH as a user of the Type B package
- Has a VDH-approved QA plan.

For each shipment, it must be clear who possesses the licensed material and is responsible for proper packaging of the radioactive materials and compliance with VDH and DOT regulations. If a licensee plans to make shipments of licensed materials in Type B packages on its own, the

licensee must be registered as a user of the package and have an VDH-approved quality assurance (QA) plan, two of the requirements under the **12VAC5-481-3000** general license.

For information about QA plans, see Revision 1 of Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," (dated June 1986).

During an inspection, the agency uses the provisions of **12VAC5-481-2980** and a "Memorandum of Understanding with DOT on the Transportation of Radioactive Material" (signed June 6, 1979) to examine and enforce various DOT requirements applicable to irradiator licensees. **Appendix Q** lists major DOT regulations.

Response from Applicant:

Item 9.9 Transportation (Check one box)

- We choose to transfer possession of radioactive material to an irradiator manufacturer, distributor, or service licensee with a VDH, NRC, or another Agreement State license who then acts as the shipper.
- OR
- Before offering a Type B package for shipment we will be registered with VDH as user of the package and obtain VDH approval of our QA program.

References: "A Review of Department of Transportation Regulations for Transportation of Radioactive Materials" can be obtained by calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4425. "Memorandum of Understanding with DOT on the Transportation of Radioactive Material" and the current version of Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material."

Item 10: Disposal, Transfer and License Termination

Item 10.1: Sealed Source Disposal and Transfer

Rule: 12VAC5-481-100; 12VAC5-481-500; 12VAC5-481-570; 12VAC5-481-571; 12VAC5-481-740; 12VAC5-481-910; 12VAC5-481-1150; 12VAC5-481-1151, 12VAC5-481-2870; 12VAC5-481-2930, 12VAC5-481-2980; 12VAC5-481-3690

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

Discussion: When disposing of sealed sources or contaminated items (caused by leaking sources), licensees must transfer them to an authorized recipient. Authorized recipients are the original manufacturer (or distributor) of the sources, a commercial firm licensed by VDH, NRC, or another Agreement State to accept radioactive waste from other persons or another specific licensee authorized to possess the licensed material (i.e., its license specifically authorizes the same radionuclide, form, and use).

If a product of the irradiator that may have been inadvertently contaminated has been shipped, the licensee must arrange to locate and survey the product for contamination. If contaminated equipment, facilities, or products are found, the licensee must arrange to have them decontaminated or properly disposed of by a VDH, NRC, or another Agreement State licensee authorized to provide these services. If the pool is contaminated, the licensee must arrange to clean up the pool until the contamination levels do not exceed the appropriate concentration in **12VAC5-481-3690 (12VAC5-481-2870)**.

Before transferring radioactive material, a licensee must verify that the recipient is properly authorized to receive it using one of the methods described in **12VAC5-481-570 D**. In addition, all packages containing radioactive sources must be prepared and shipped according to VDH and DOT regulations. Records of the transfer must be maintained as required by **12VAC5-481-100, 12VAC5-481-571 and 12VAC5-481-2930**.

Because of the difficulties and costs associated with disposal of sealed sources, applicants should preplan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement. The licensee should establish and include waste disposal procedures in its radiation safety program.

Response from Applicant:

Item 10.1 Sealed Source Disposal And Transfer (Check Box)

We will return the source to the manufacturer for disposal or transfer the device to a specific licensee authorized to receive radioactive material.

Item 10.2: Termination of Activities

Rule: 12VAC5-481-100; 12VAC5-481-450; 12VAC5-481-500; 12VAC5-481-510; 12VAC5-481-570; 12VAC5-481-571; 12VAC5-481-1161

Criteria: The licensee must do the following:

- Notify the agency, in writing, within 60 days of:
 - The expiration of its license
 - A decision to permanently cease licensed activities at the entire site (regardless of contamination levels)
 - A decision to permanently cease licensed activities in any separate building or outdoor area, if they contain residual radioactivity making them unsuitable for release according to VDH requirements
 - No principal activities having been conducted at the entire site under the license for a period of 24 months
 - No principal activities having been conducted for a period of 24 months in any separate building or outdoor area, if they contain residual radioactivity making them unsuitable for release according to VDH requirements.
- Submit a decommissioning plan, if required by **12VAC5-481-510**.

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

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

For guidance on the disposition of licensed material, see the Item 10.1 Sealed Source Disposal and Transfer. For guidance on decommissioning records, see Item 7.2 Financial Assurance and Record Keeping for Decommissioning.

Response from Applicant:

Item 10.2 Termination Of Activities (Check box)	
<input type="checkbox"/>	We will notify the agency, in writing, within 60 days of the decision to permanently cease radioactive material use per 12VAC5- 481-510 D .

Item 11: License Fees

Rule: 12VAC5-481-2690; 12VAC5-490

An application and required fee must be submitted before start of construction (see **12VAC5-481-2690**). This will allow regulatory agencies to inspect the construction of the facility as it is being built. On VDH form, 'Application for a Radioactive Material License Authorizing the Use of **12VAC5-481 Part XII Irradiators**', enter the fee category and the amount. Enclose fee with the application.

Response from Applicant:

SPECIFIC LICENSE FEE	
Item 11 License Fees (Refer to 12VAC5-490 .)	
Category:	Application fee enclosed (for new applications): <input type="checkbox"/> Yes <input type="checkbox"/> No Amount Enclosed _____

Item 12: Certification

Individuals acting in a private capacity are required to sign and date VDH form, 'Application for a Radioactive Material License Authorizing the Use of **12VAC5-481 Part XII Irradiators**'.

Otherwise, senior representatives of the corporation or legal entity filing the application should sign and date VDH form, 'Application for a Radioactive Material License Authorizing the Use of 12VAC5-481 Part XII Irradiators'.

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.

For converted teletherapy units, **Appendix R** lists specific sections of the regulations, the rationale and acceptable alternatives, and the wording of the license condition granting the exemption.

Response from Applicant:

CERTIFICATION (To be signed by an individual authorized to make binding commitments on behalf of the applicant.)	
Item 12	
I hereby certify that this application was prepared in conformance with 12VAC5-481, 'Virginia Radiation Protection Regulations' and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.	
SIGNATURE - Applicant Or Authorized Individual	Date signed:
Print Name and Title of above signatory	

Appendix A:

**VDH Form, 'Application for a Radioactive
Material License Authorizing the Use of
12VAC5-481 Part XII Irradiators'**



**APPLICATION FOR A RADIOACTIVE MATERIAL LICENSE
 AUTHORIZING THE USE OF 12VAC5-481 PART XII IRRADIATORS**

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

Instructions – Complete all items if this is an initial application or an application for renewal of a license. Refer to VAREG “Guidance for 12VAC5-481 Part XII Irradiators.” Use supplementary sheets where necessary. Retain one copy and submit original of the entire application to: Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219.

APPLICATION TYPE

Item 1 Type Of Application (Check one box)

New License Renewal License Number _____

CONTACT INFORMATION

Item 2 Name And Mailing Address Of Applicant:

Item 3 Person To Contact Regarding Application:

Applicant’s Telephone Number (Include area code):
 () - x

Contact’s Telephone Number (Include area code):
 () - x

LOCATION OF RADIOACTIVE MATERIAL

Item 4 Address(es) Where Licensed 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

RADIATION SAFETY OFFICER

Item 5. Radiation Safety Officer (RSO) (Check one box and attach evidence of training and experience)

Name: _____

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

Before obtaining radioactive material, the proposed RSO will have successfully completed training as described in Appendix G of VAREG ‘Guidance for 12VAC5-481 Part XII Irradiators’. Before being named as the RSO, future RSOs will have successfully completed training as described in Appendix G of VAREG ‘Guidance for 12VAC5-481 Part XII Irradiators’

OR

Alternative information demonstrating that the proposed RSO is qualified by training and experience is attached. Before being named as the RSO, future RSOs will have successfully completed training as described in Appendix G of VAREG ‘Guidance for 12VAC5-481 Part XII Irradiators’.

AND

Description of organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities has been attached as required by 12VAC5-481-2680.

IRRADIATOR OPERATORS AND INDIVIDUALS WHO REQUIRE UNESCORTED ACCESS

Item 6 Irradiator Operators (Check all that apply)

- Before using radioactive material, irradiator operators will have successfully completed an irradiator manufacturer's course for operators specific to the irradiator that the applicant intends to use
OR
- Before using radioactive material, Irradiator operators will have received training as described in Appendix G in VAREG 'Guidance for 12VAC5-481 Part XII Irradiators' and as required by 12VAC5-481-2830.
AND
- The safety performance of each irradiator operator must be evaluated and reviewed at least every twelve months to ensure that regulations, license conditions, and operating and emergency procedures are followed as required by 12VAC5-481-2830.
AND
- Before entering the radiation room of an irradiator or area around the pool of an underwater irradiator, individuals who require unescorted access will be instructed and tested in precautions to avoid radiation exposure and their proper response to alarms. Training may include the subjects described in Appendix G in VAREG 'Guidance for 12VAC5-481 Part XII Irradiators.'
OR
- A description of the training and experience for proposed operators and individuals who require unescorted access is attached.

RADIOACTIVE MATERIAL

Item 7 Radioactive Material (Attach additional pages if necessary)

<p>ELEMENT AND MASS NUMBER</p> <p><input type="checkbox"/> Cobalt-60 <input type="checkbox"/> Strontium-90 <input type="checkbox"/> Cesium-137 <input type="checkbox"/> Other Isotope (please specify):</p>	<p>IRRADIATOR MANUFACTURER AND MODEL NUMBER</p>
<p>MAXIMUM QUANTITY (Not to exceed either the maximum activity per source or device as specified in the Sealed Source and Device Registration Certificate)</p>	<p>MAXIMUM AMOUNT OF DEPLETED URANIUM (KG)</p>
<p>SEALED SOURCE MANUFACTURER OR DISTRIBUTOR AND MODEL NUMBER</p>	<p>DEVICE MANUFACTURER OR DISTRIBUTOR AND MODEL NUMBER</p>
<p>MAXIMUM ACTIVITY PER SOURCE FOR DRY-SOURCE STORAGE</p>	<p>INTENDED USE: (Specific description of use of each type of irradiator requested. A description of purposes and safety analysis to support safe use has been attached)</p>

FINANCIAL ASSURANCE

- We will submit the necessary documentation
OR
- N/A

FACILITIES AND EQUIPMENT

Item 8 Facilities And Equipment (Check all that apply)

Item 8.1 Description of the Facility and Site

- Diagrams of radioactive material area(s) are attached.

AND EITHER

- We will ensure that each area where an irradiator is located corresponds to the 'Conditions of Normal Use' and 'Limitations and/or Other Considerations of Use' on the applicable irradiator's Sealed Source and Device Registration Certificate; the floor beneath the irradiator is secured to prevent unauthorized access or removal; and each area where a irradiator is located is equipped with an automatically operated fire detection and control system (sprinkler, chemical, or gas) or the location of the area and other controls ensure a low-level radiation risk attributable to fires.

OR

- We will submit alternative information; which includes the justification for placing an irradiator in an area that does not correspond to the 'Conditions of Normal Use' and the 'Limitations and/or Other Considerations of Use.'
-

Item 8.2 Access Control (Check boxes)

- For Underwater Irradiators**, we will submit specific information describing the access control system and how it works that demonstrates compliance with the requirements of **12VAC5-481-2730**. Specific drawings or sketches should be submitted, as appropriate.

OR

- For Panoramic Irradiators**, we will describe the facility alarm systems and describe the lock and key system for controlling source movement and discuss how it meets the requirements of **12VAC5-481-2770**.
-

Item 8.3 Shielding (Check boxes)

For Panoramic Irradiators:

- We will describe the shielding to be used and its composition
AND
- We will submit a diagram showing the configuration of shielding including walls and the ceiling and indicate the thickness of each and penetrations in the shielding
AND
- If any accessible areas outside the shield are expected to have a dose rate exceeding 0.02 mSv (2 mrem) per hour, we will identify the areas and explain how access will be controlled
AND
- For requests to possess more than 2×10^{17} Bq (5 million curies), we will submit an evaluation of the effects of heating of the shielding walls by the irradiator sources

For Panoramic Irradiators constructed after July 1, 1993:

- We have identified the building code requirements to which shielding walls will be built and inspections of the construction which will be performed by local authorities so that they do not adversely impact VDH requirements.

For Underwater Irradiators, no response is required from the applicant in a license application.

Item 8.4 Fire Protection (Check boxes)

For Panoramic Irradiators, describe:

- The type and location of the heat and smoke detectors to be used to detect a fire in the radiation room
AND
- The alarms to alert personnel trained to summon assistance
AND
- How the sources will automatically become fully shielded if a fire is detected
AND
- How the heat and smoke detectors will be tested.

For Underwater Irradiators, no response is required, since the sources are always underwater and not subject to damage by fire.

Item 8.5 Radiation Monitors (Check boxes)

- We will describe the location and type of radiation monitors that will be used to meet the requirements of 12VAC5-481-2730, 12VAC5-481-2760 and 12VAC5-481-2870.

AND

- We will describe the location and types of alarms and those individuals who are trained to respond to those alarms. Diagrams and sketches should be used, as appropriate.

AND

- We will discuss the alarm set-points or the methods for establishing the alarm set-points.

For all Irradiators constructed after July 1, 1993:

- We have verified the operability of radiation monitors and related alarms and interlocks prior to loading the sources per Appendix J, 'Construction Monitoring and Acceptance Testing' of VAREG 'Guidance for 12VAC5-481 Part XII Irradiators.'

AND

- We will describe the evaluation performed to meet 12VAC5-481-2810 on detector location and sensitivity and the acceptance testing that will be performed to meet 12VAC5-481-2820.

Note: All Underwater Irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of 12VAC5-481-2760.

Item 8.6 Irradiator Pools (Check boxes)

For all Pool Irradiators, describe:

- The high and low water-level indicators and their locations

AND

- The purification system for the pool with an explanation of why it is capable of maintaining pool water conductivity less than 20 microsiemens per centimeter

AND

- The means to replenish pool water

AND

- The barrier used during normal operation to prevent personnel from falling into the pool

AND

- How high radiation doses from radiation streaming will be avoided when using long-handled tools or poles (use sketches if appropriate).

AND

- If the pool has outlets more than 0.5 meter below the surface that could allow water to drain out of the pool, the means of preventing inadvertent excessive loss of pool water (in this context outlets do not include transfer tubes between adjacent pools because the transfer tubes do not provide a means to allow water to drain out of the pools).

For Irradiators licensed after July 1, 1993, describe:

- The pool liner. If no water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool is used, explain why the pool has a low likelihood of substantial leakage and how decontamination could be accomplished if necessary.

Item 8.7 Source Rack (Check boxes)

- We will submit procedures for ensuring source rack protection. If the product moves on a product conveyer system, describe the source rack protection to be provided to prevent products and product carriers from touching the source rack or mechanism that moves the rack.

AND

- We will provide diagrams or sketches of those systems, if appropriate.

Item 8.8 Power Failures (Check boxes)

For Panoramic Irradiators,

- We will describe how loss of power will affect the lock on the doors in the radiation room.

AND

- If construction began after July 1, 1993, we will describe how the sources are automatically returned to the shielded position if offsite power is lost for longer than 10 seconds.

For Underwater Irradiators, no response is required.

RADIATION SAFETY PROGRAM

Item 9 Radiation Safety Program

Item 9.1 Audit Program

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

Item 9.2 Radiation Monitoring Instruments (Check one box)

- We will use instruments that meet the radiation monitoring instrument specifications published in Appendix K of VAREG 'Guidance for 12VAC5-481 Part XII Irradiators'. Additionally, each survey meter will have been calibrated by the manufacturer or other person authorized by VDH, the NRC, or another Agreement State to perform survey meter calibrations no more than 12 months before the date the meter is used.

OR

- We will use instruments that meet the radiation monitoring instrument specifications published in Appendix K of VAREG 'Guidance for 12VAC5-481 Part XII Irradiators'. Additionally, we will implement the model survey meter calibration program published in Appendix L of VAREG 'Guidance for 12VAC5-481 Part XII Irradiators' and we ensure that each survey meter will have been calibrated no more than 12 months before the date the meter is used.

OR

- We will have access to survey equipment and/or procedures for ensuring that interlocks function, as required, to return moving irradiator sources to the shielded position and/or determining source shielding integrity after an incident involving the irradiator.

Item 9.3 Material Receipt And Accountability (Check box)

- We will submit a description of procedure(s) for ensuring material accountability.

Item 9.4 Occupational Dose (Check one box)

- 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 and in accordance with 12VAC5-481-2850.

OR

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

Item 9.5 Public Dose

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

Item 9.6 Operating And Emergency Procedures (Check all that apply)

- We will develop, implement, maintain and distribute operating and emergency procedures that will meet the Criteria in the section titled 'Operating and Emergency Procedures' in VAREG 'Guidance for 12VAC5-481 Part XII Irradiators'. (Procedures are attached)

OR

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

AND

- Licensees must have and follow emergency or abnormal event procedures, appropriate for the irradiator type as required by 12VAC5-481-2840.

AND

- For routine operations: We will provide an outline that specifically state the radiation safety aspects of the written operation procedures (i.e., those procedures listed in 12VAC5-481-2840)

Item 9.7 Leak Tests (Check one box for each type)

For Dry-Source-Storage Irradiators:

Leak tests will be performed at intervals not to exceed 6 months and will be performed by an organization authorized by VDH, NRC, or another Agreement State to either perform the entire leak test sequence for other licensees or provide leak test kits to dry-source-storage licensee as required by **12VAC5 481-2870**.

OR

We will perform leak testing and sample analysis and will follow the model procedures in Appendix P of VAREG 'Guidance for **12VAC5-481 Part XII Irradiators**'. (Procedures are attached)

OR

We will submit alternative procedures. (Procedures are attached)

For Pool Irradiators:

We will include a description of equipment, procedures, and sensitivity of method that will be used to check for contamination by analysis of a sample of pool water.

OR

We will include a description of equipment, procedures, and sensitivity of method that will be used to check for contamination by continuous monitoring.

Item 9.8 Inspection and Maintenance Checks (Check one box)

We will implement and maintain procedures for routine inspection and maintenance checks of our irradiators according to each manufacturer's (or distributor's) written recommendations and instructions. We will attach a description of inspection and maintenance checks, including the frequency of the checks as required by **12VAC5-481-2880**.

OR

Alternative procedures are attached.

Item 9.9 Transportation (Check one box)

We choose to transfer possession of radioactive material to an irradiator manufacturer, distributor or service licensee with a VDH, NRC, or another Agreement State license who then acts as the shipper.

OR

Before offering a Type B package for shipment we will be registered with VDH as user of the package and obtain VDH approval of our QA program.

DISPOSAL, TRANSFER AND LICENSE TERMINATION

Item 10 Disposal, Transfer and License Termination

Item 10.1 Sealed Source Disposal And Transfer (Check Box)

We will return the source to the manufacturer for disposal or transfer the device to a specific licensee authorized to receive radioactive material.

Item 10.2 Termination Of Activities (Check box)

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

SPECIFIC LICENSE FEE

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

Category: _____ Application fee enclosed (for new applications):

Yes No Amount Enclosed

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

Item 12

I hereby certify that this application was prepared in conformance with **12VAC5-481**, 'Virginia Radiation Protection Regulations' and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.

SIGNATURE - Applicant Or Authorized Individual

Date signed:

Print Name and Title of above signatory

Appendix B:

**VDH Form, 'Certificate of Disposition of
Materials'**



CERTIFICATE OF DISPOSITION OF MATERIALS

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

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

CONTACT INFORMATION

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

TERMINATION AND DISPOSITION INFORMATION

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

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

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

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

Transferred to: Name Address

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

Issued by (Licensing Agency):

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

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

Other (Attach additional pages)

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

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

Name:

Address:

Contact Person Telephone Number: () - X

Additional remarks (Attach additional pages if necessary.)

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

Item 10.

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

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

Print Name and Title of above signatory.

Appendix C:

Sample Correspondence of Delegation Letter

Model Delegation of Authority

Memo

To: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with the rule. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Virginia Department of Health, Radioactive Materials Program at anytime. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

Signature of Management Representative

I accept the above responsibilities,

Signature of Radiation Safety Officer

cc: Affected department heads.

Appendix D:
**Information Needed for Transfer of
Control Application**

Information Needed for Transfer of Control Application

Licensees must provide full information and obtain the agency'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.

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

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

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

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

**Suggested Wording for a Statement of
Intent for a VDH Licensee**

Suggested Wording for a Statement of Intent for a VDH Licensee

[date]

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

STATEMENT OF INTENT

As [Title] of [Licensee Name] I exercise express authority and responsibility to approve funding for decommissioning activities associated with operations authorized by Virginia Department of Health Radioactive Material License No. [License No.]. This authority is established by [Name of Document(s) Governing Control of Funds]. Within this authority, I intend to have funds made available when necessary in an amount up to [Dollar Amount] to decommission [Description of Facilities]. I intend to request and obtain these funds sufficiently in advance of decommissioning to prevent delay of required activities.

A copy of [Name of Documents] is attached as evidence that I am authorized to represent [Licensee Name] in this transaction.

[SIGNATURE]
[NAME]
[TITLE]

Appendix F:

**Irradiation of Explosive Materials or
Greater Than Small Quantities of
Flammable Materials**

Irradiation of Explosive Materials or Greater Than Small Quantities of Flammable Materials

Explosive Materials

Irradiation of explosive materials is prohibited under **12VAC5-481 'Virginia Radiation Protection Regulations', Part XII, 'Licensing and Radiation Safety Requirements for Irradiators'** unless the applicant has received prior written authorization from VDH. If an applicant requests authorization to irradiate explosive materials, he or she must be able to demonstrate that detonation of the explosive would not rupture the irradiator sealed sources, injure personnel, damage safety systems, or cause radiation overexposure of personnel.

Greater Than Small Quantities of Flammable Materials

Prior written authorization from VDH is required by **12VAC5-481-2920** before irradiation of more than small quantities of flammable materials with a flash point below 60°C (140°F) in a panoramic irradiator. As defined in the National Fire Code NFPA 30, "Flammable and Combustible Liquids Code," published by the National Fire Protection Association, the flash point is "*the minimum temperature at which a liquid gives off vapor in sufficient concentration to form an ignitable mixture with air near the surface of the liquid...*" According to the NFPA 30 classification system, Class I and Class II liquids have flash points below 60°C (140°F). The flash points of many substances are tabulated in National Fire Code NFPA 325M, "Fire Hazard Properties of Flammable Liquids, Gases, and Volatile Solids." Flash points are also specified on the Material Safety Data Sheets for industrial chemicals, when applicable. Examples of common flammable liquids with a flash point below 60°C (140°F) are acetone, benzene, most alcohols, number two fuel oil, gasoline, kerosene, toluene, turpentine, and any flammable gas. The agency is concerned about irradiating flammable materials which may cause an explosion. If the flash point of a flammable liquid is exceeded, the concentration of the vapor in air could exceed the flammable limit and the potential for an explosion could exist.

VDH considers that compliance with the requirements in **12VAC5-481-2720, 12VAC5-481-2750, 12VAC5-481-2790, 12VAC5-481-2810, 12VAC5-481-2820 and 12VAC5-481-2840** will provide adequate protection against radiological impacts arising from a fire. With an energetic explosion, however, applicants should consider the possibility of direct damage to the source encapsulation or to the source rack preventing it from being lowered to the shielded position.

A "small quantity" of flammable material can be defined as a quantity of flammable material that, when dispersed evenly throughout the radiation room with no loss to ventilation, would have a concentration below the lower flammable limit concentration. Although local concentrations could exceed the average room concentration, the movement of air into and out of the radiation room provides a margin of safety. In addition, the time required to vaporize all the material also adds to the margin of safety. Further, small pockets of flammable vapor will contain quantities of energy too small to provide a force strong enough to significantly damage the irradiator. Given these factors, the definition of small quantity is considered to be conservative enough to ensure safe operation of an irradiator.

Special precautions must be taken when irradiating cryogenic material. The hazard from cryogenic irradiation occurs when air condenses or freezes (possibly insidiously without detection) on cold surfaces during irradiation. While the exact details are uncertain, oxygen in the air is converted by the radiation to ozone. Under certain circumstances (often during a subsequent warm-up), the ozone decomposes or reacts with other agents explosively. If cryogenic material is to be irradiated the applicant must submit procedures for ensuring the safe handling of such material.

Example of determining a small quantity of flammable material

This example considers the irradiation of isopropyl alcohol in a radiation room whose total volume is 100 m^3 . NFPA 325M states that the lower flammable limit for isopropyl alcohol is 2% by volume, the specific gravity of the liquid is 0.8, and the vapor density relative to that of air is 2.1. The density of air is 1.293 kg/m^3 . The volume of isopropyl alcohol in the room at the lower flammable limit will be 2% of 100 m^3 , which is equal to 2 m^3 . The weight will be $2 \text{ m}^3 \times 1.293 \text{ kg/m}^3 \times 2.1$ (density relative to air) = 5.43 kg. With a specific gravity of 0.8, the volume of the liquid isopropyl alcohol would be 6.79 liters. If the liquid mixture were 70% isopropyl alcohol and 30% water, the volume of a small quantity would be $6.79/0.7 = 9.7$ liters. Thus, in a radiation room with a volume of 100 m^3 , a volume less than 9.7 liters of 70% pure isopropyl alcohol (exposed to the direct radiation beam) can be considered a small quantity because the flammable limit could not be reached in any significant volume even if there were no ventilation.

If the applicant irradiates small quantities of flammable material, the licensee's records should demonstrate that the above criterion for small quantities has been met, including how the licensee limited the quantity of flammable material in the radiation room at one time.

If the quantity to be exposed to the direct beam at any one time would exceed a small quantity, it is necessary to consider whether the concentration of flammable vapor in the room air could exceed the lower flammable limit. If product movement through the irradiator stopped and the radiation sources could not be returned to the shielded position, the temperature of the irradiated product would rise, the vapor pressure of the flammable material would increase, and that pressure might cause the containers to leak and release flammable vapor into the room air. If ventilation were insufficient, the flammable vapor concentration might exceed the lower flammable limit and a spark could cause the mixture to explode.

Requests for approval to irradiate more than small quantities of flammable material

The applicant must demonstrate that it is unlikely that the concentration of flammable vapor in air in a significant volume of the room would exceed the lower flammable limit. There are two methods to do this. The first method is to demonstrate that no single failure would be likely to cause the product to become immobilized in the radiation room and prevent the sources from being returned to the shielded position. Such a situation theoretically might arise if the product carriers became jammed and pushed into the source rack preventing its return to the shielded position. The second method is to demonstrate that even if the product became immobilized and the source rack could not be returned to the shielded position, the ventilation system would

prevent the concentration of flammable vapor in a significant volume of the room air from reaching the lower flammable limit.

If an applicant is applying for authorization to irradiate more than a small quantity of flammable material, the application should include all of the following information:

- Name of the flammable material that has a flash point below 60°C (140°F) and its flash point
- Its flammable limit as percent by volume in air
- Its specific gravity as a liquid
- Its vapor density relative to that of air
- Maximum quantity to be in the direct radiation beam in the radiation room at any one time
- Description of the packaging for the product.

In addition, the application should:

EITHER

Describe why a single failure is unlikely to cause immobilization of the product being irradiated with the simultaneous inability to return the sources to the shielded position.

OR

Describe why the ventilation system will prevent the concentration of vapor in air from exceeding the lower flammable limit in a significant volume of the room if the product is immobilized and the sources cannot be returned to the shielded position. If this second approach is taken, the applicant should also provide a procedure to return the source to the shielded position and remove the product from the radiation room if the ventilation system fails. The procedure should also identify the means to detect ventilation system failure.

Note: This information was taken from Oak Ridge National Laboratory Report ORNL/M-260, DE87 002877, "Safety Analysis Report for the National Low-Temperature Neutron Irradiation Facility (NLTNIF) at the ORNL Bulk Shielding Reactor (BSR)," June 1986.

Note: Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, P. O. Box 9146, Quincy, MA 02269-9959 (Telephone No. 1-800-344-3555).

Appendix G:

**Training for Radiation Safety Officers
and Irradiator Operators**

Training for Radiation Safety Officers and Irradiator Operators

Course Content

Instruction may be in the form of lecture, videotape, or self-study emphasizing practical subjects important to safe use of irradiators:

- **Radiation Safety:**
 - External radiation vs. radioactive contamination
 - Internal vs. external exposure
 - Biological effects of radiation (e.g., why large radiation doses must be avoided)
 - Units of radiation dose
 - Types and relative hazards of radioactive material possessed
 - ALARA concept
 - Use of time, distance, and shielding to minimize exposure (e.g., how shielding and access controls prevent large doses)
 - Proper use of survey meters and personnel dosimeters.
- **Regulatory Requirements:**
 - Applicable regulations
 - VDH dose limits
 - License conditions, amendments, renewals
 - Locations of use and storage of radioactive materials
 - Material control and accountability
 - Annual audit of radiation safety program
 - Transfer and disposal
 - Record keeping
 - Case histories of accidents or problems involving irradiators
 - Handling incidents
 - Recognizing and ensuring that radiation warning signs are visible and legible
 - Licensing and inspection by VDH
 - Need for complete and accurate information
 - Employee protection
 - Deliberate misconduct.
- **Practical Explanation of the Theory and Operation for Irradiators:**
 - Basic function of the irradiator
 - Radiation safety features of an irradiator
 - Operating and emergency procedures which the individual is responsible for performing
 - Routine vs. non-routine maintenance
 - Lock-out procedures
 - How an irradiator is designed to prevent contamination.

On-the-job or simulator training must be done under the supervision of a qualified irradiator operator:

- Supervised Hands-on Experience Performing:
 - Operating procedures which the individual is responsible for performing
 - Test runs of emergency procedures which the individual is responsible for performing
 - Routine maintenance
 - Lock-out procedures.
- Training for an RSO should include at least 3 months (full-time equivalent) of experience at the applicant's irradiator or at another irradiator of a similar type. The 3 months of experience may include preoperational involvement, such as acceptance testing, while the irradiator is being constructed.

Course Examination

Written examination designed to verify an individual's competency and understanding of the subject matter (e.g., 25 to 50 question, closed-book written test with 70% as passing grade). Emphasis on radiation safety of irradiator operations and maintenance, licensee operating and emergency procedures that the individual will be responsible for performing, and other operations necessary to safely operate the irradiator without supervision. Review of correct answers to missed questions with prospective irradiator operators immediately following the scoring of the test.

Training Assessment

Management will ensure that potential RSOs and authorized operators are qualified to work independently with irradiators. This must be demonstrated by written examination and by direct observations.

Course Instructor Qualifications

Instructor should have either:

- Bachelor's degree in a physical or life science or engineering
- Successful completion of an irradiator manufacturer's course for users (or equivalent)
- Successful completion of an 8 hour radiation safety course and
- 8 hours hands-on experience with irradiators

OR

- Successful completion of an irradiator manufacturer's course for users (or equivalent)
- Successful completion of 40 hour radiation safety course; and
- 30 hours of hands-on experience with irradiators.

Note:

- Licensees must maintain records of training (12VAC5-481-2930).
- Additional training is required for those applicants intending to perform non-routine operations such as source loading and unloading. See Appendix I, "Non-Routine Operations."

Appendix H:
Typical Duties and Responsibilities
of the Radiation Safety Officer

Typical Duties and Responsibilities of the Radiation Safety Officer

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

- Stopping activities that the RSO considers unsafe
- Keeping exposures ALARA
- Developing, maintaining, distributing, and implementing up-to-date operating and emergency procedures
- Ensuring that individuals associated with irradiator operations are properly trained and evaluated
- Ensuring that non-routine operations (See **Appendix I**) for irradiators are consistent with the limitations in the license, the Sealed Source and Device Registration Certificate(s), and the manufacturer's written recommendations and instructions
- Analyzing potential safety consequences of non-routine operations before conducting any such activities that have not been previously analyzed
- Ensuring non-routine operations are performed by the manufacturer or person specifically authorized by VDH, NRC, or another Agreement State to perform those operations
- Ensuring that personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained by the licensee
- Maintaining documentation that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or provide personnel monitoring devices
- Notifying proper authorities of incidents such as damage to or malfunction of irradiators, fire, loss or theft of licensed materials (See also Appendix O)
- Investigating emergencies and abnormal events involving the irradiators (e.g., malfunctions or damage), identifying cause(s), implement appropriate and timely corrective action(s)
- Performing radiation safety program audits at least every 12 months and developing, implementing, and documenting timely corrective actions
- Ensuring transport of licensed material according to all applicable DOT requirements
- Ensuring proper disposal of licensed material
- Maintaining appropriate records associated with irradiator operations
- Maintaining an up-to-date license and timely submission of amendment and renewal requests
- Ensuring that when the licensee identifies violations of regulations or license conditions or program weaknesses, corrective actions are developed, implemented, and documented

Appendix I:

**Information Needed to Support
Applicant's Request to Perform
Non-Routine Operations**

Information Needed to Support Applicant's Request to Perform Non-Routine Operations

Non-routine operations may include the following:

- Source loading, unloading and repositioning
- Troubleshooting the control console
- Clearing stuck source racks
- Investigating/remediating removable contamination/leaking sources
- (Re)installing source cables
- Any other activity during which personnel could receive radiation doses exceeding VDH limits.

If these operations are not performed properly with attention to radiation safety principles, the irradiator may not operate as designed and personnel performing these tasks could receive lethal radiation doses.

Applicants wishing to perform non-routine operations must use personnel with special training and follow appropriate procedures consistent with the manufacturer's written instructions and recommendations that address radiation safety concerns (e.g., use of radiation survey meter, personnel dosimetry). Accordingly, provide the following information:

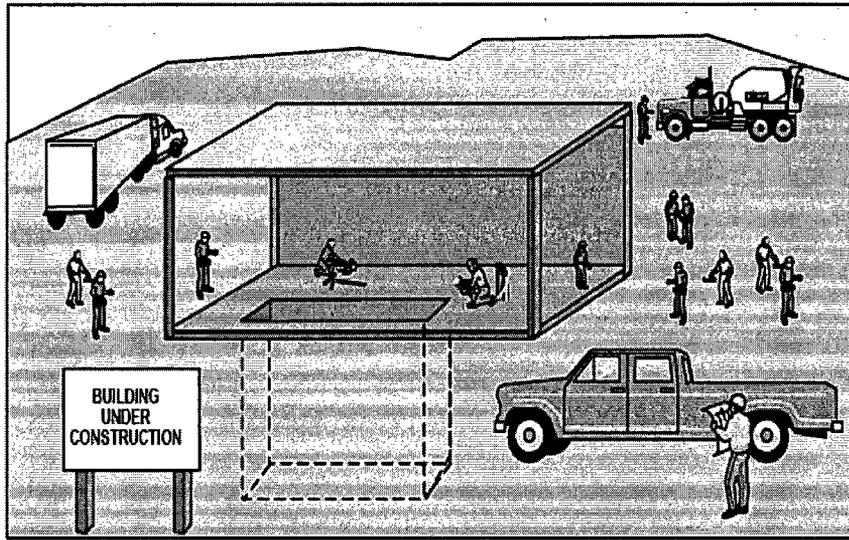
- Describe which non-routine operations will be performed. The principal reason for obtaining this information is to assist in the evaluation of the qualifications of individuals who will conduct the work and the radiation safety procedures they will follow.
- Identify who will perform non-routine operations and their training and experience applicable to these operations. Acceptable training would include manufacturers' courses for non-routine operations or equivalent.
- Submit procedures for non-routine operations. These procedures should ensure the following:
 - doses to personnel and members of the public are within regulatory limits and ALARA (e.g., use of shielding and adequate planning when working with unshielded sources)
 - manufacturer's written instructions and recommendations are followed
 - planned special exposure requirements (**12VAC5-481-690**), if applicable, are met
 - operations involving source loading, unloading, and repositioning include recording the rack position of each source and surveying all empty or loaded source transport containers for removable contamination to prevent the introduction of radioactive contaminants into the irradiator.
- Confirm that individuals performing non-routine operations will wear whole body radiation dosimetry, if appropriate.
- Describe steps to be taken to ensure that radiation levels in areas where non-routine operations will take place do not exceed **12VAC5-481-720** limits. For example, applicants can do the following:
 - commit to performing surveys with a survey instrument;
 - specify where and when surveys will be conducted during non-routine operations; and
 - commit to maintaining, for 3 years from the date of the survey, records of the survey (e.g., who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements), as required by **12VAC5-481-1050**.

Appendix J:
**Construction Monitoring and
Acceptance Testing**

Construction Monitoring and Acceptance Testing

To ensure that irradiators and their components are built and installed as designed, 12VAC5-481-2820 requires that, for irradiators whose construction began after July 1, 1993, licensees conduct monitoring and acceptance testing before loading sealed sources. **Figure 1** illustrates this point and **Table 6** correlates the components to be checked and the types of tests with the type of irradiator to which the requirement applies.

Figure 1: Construction Monitoring and Acceptance Testing. Before loading sealed sources, irradiator licensees must ensure that the as-built irradiator meets design criteria.



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Table 6: Construction Monitoring and Acceptance Testing

Irradiator Elements	Irradiator Type	Licensee Requirements
Shielding	Panoramic	Monitor the construction of the shielding to make sure that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.
Foundations	Panoramic	Monitor the construction of the foundations to verify that their construction meets design specifications.
Pool Integrity	Pool	Verify that the pool meets design specifications including requirements in 12VAC5-481-2780 and test the integrity of the pool.
Water Handling System	Pool	Verify that the water purification system, the conductivity meter, and the water level indicators operate properly (water level controls should be checked, if installed).

Irradiator Elements	Irradiator Type	Licensee Requirements
Radiation Monitors	All	Verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by 12VAC5-481-2760 .
	Pool	Verify the proper operation of the radiation monitors and the related alarm if used to meet 12VAC5-481-2870 .
	Underwater	Verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by 12VAC5-481-2760 .
Source Rack	Panoramic	Test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power.
	Irradiation with Product Conveyor Systems	Observe and test the operations of the conveyor system to ensure that the requirements in 12VAC5-481-2790 are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.
Access Control	Panoramic	Test the completed access control system to ensure that it functions as designed and that all alarms, controls, and interlocks work properly.
Fire Protection	Panoramic	Test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee must test the operability of the fire extinguishing system. It is not necessary that licensees turn on extinguishers (i.e., water or chemicals) during tests of the operability of their fire protection systems.
Source Return	Panoramic	Demonstrate that the source racks can be returned to their fully shielded positions without offsite power.
Computer Systems	Panoramic, that use a computer system to control the access control system	Verify that the access control system will operate properly if offsite power is lost and verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.
Wiring	Panoramic	Verify that the electrical wiring and electrical equipment that were installed meet the design specifications (e.g. radiation-resistant wiring installed in appropriate locations and according to code).

Appendix K:

**Suggested Audit Checklist for
12VAC5-481 Part XII Irradiators**

Suggested Audit Checklist for 12VAC5-481 Part XII

Irradiators

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 their activities and activities which have not occurred since the last audit need not be reviewed at the next audit.

Licensee's name: _____ License No. _____

Date of This Audit _____
_____ Date _____

(Auditor Signature) _____
_____ Date _____

(Management Signature) _____

Audit History

- A. Last audit of this location conducted on (date)
- B. Were previous audits conducted at intervals not to exceed least every 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?
- B. If ownership changed or bankruptcy filed, was VDH prior consent obtained or was VDH notified?
- C. Radiation Safety Officer
 - 1. If the RSO was changed, was license amended?
 - 2. Does new RSO meet the licensee's training requirements?
 - 3. Is RSO fulfilling his/her duties?
 - 4. To whom does RSO report?
- D. If the designated contact person for the agency changed, was the agency notified?

E. Sealed Sources and Devices

1. Does the license authorize all of the VDH regulated radionuclides contained in irradiators?
2. Have copies of (or access to) SSD Certificates?
3. Are the sealed sources, and if applicable, devices in accordance with the description in the Sealed Source and Device (SSD) Registration Certificates?
4. Have manufacturers' manuals for operation and maintenance?
5. Are the actual uses of the irradiator consistent with the authorized uses listed on the license?
6. Are the sealed sources used under conditions specified in the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" on the SSD Registration Certificates?

Training and Instructions to Workers

- A. Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed per **12VAC5-481-2270**? Refresher training provided, as needed? Records maintained?
- B. Did each individual permitted to operate the irradiator without a supervisor present, receive instruction according to the license commitments and **12VAC5-481-2830** before operating the irradiator?
- C. Are records of training, tests, safety reviews, and annual evaluations maintained for each authorized irradiator operator? [**12VAC5-481-2930**]
- D. Did individuals who perform non-routine operations receive training before performing these operations?
- E. Did interviews reveal that individuals know the emergency procedures?
- F. Did this audit include observations of irradiator operations?
- G. Do workers know requirements for the following:
 1. the radiation safety program
 2. annual dose limits
 3. appropriate VDH Forms
 4. 10% monitoring threshold
 5. dose limits to embryo/fetus and declared pregnant worker
 6. grave danger posting?

Radiation Survey Instruments And Radiation Monitors

- A. Are all portable survey meters calibrated at least annually to an accuracy of $\pm 20\%$ for the gamma energy of the sources in use? [**12VAC5-481-2860**]
- B. Are portable survey meters of a type that does not saturate and read zero at high dose rates?

[12VAC5-481-2860]

- C. Are calibration records maintained?
- D. Are all operable survey instruments able to detect 0.5 microsievert (0.05 mrem) per hour?
- E. Has the licensee evaluated the location and sensitivity of the radiation monitor to detect sources carried by the product conveyor system for automatic conveyor systems? [12VAC5-481-2760]
- F. Has the licensee tested the operability and sensitivity of monitor used to detect the presence of high radiation levels in the radiation room before personnel entry at frequency specified in license application?
- G. Has the licensee tested the operability and sensitivity of monitor used to detect contamination of pool water due to leaking sources? (Frequency of checks as specified in license application?)
- H. For underwater irradiators not in a shielded radiation room, has the licensee tested the operability and sensitivity of monitor used to detect abnormal radiation levels? (Frequency of checks as specified in license application?)

Conductivity Meters

- A. Are appropriate operable conductivity meters possessed and used?
- B. Are conductivity meters calibrated at least annually? [12VAC5-481-750 and 12VAC5-481-2860]

Sealed Source Accountability Program

- A. Are records maintained showing the receipt, location, transfer, and disposal of each sealed source? [12VAC5-481-100, 12VAC5-481-571 and 12VAC5-481-2930]
- B. Is material accountability program as described in application being implemented?

Personnel Radiation Protection

- A. Are ALARA considerations incorporated into the radiation protection program?
[12VAC5-481-630]
- B. Is documentation kept showing that unmonitored individuals receive less than 10% of limit?
[12VAC5-481-760 and 12VAC5-481-1050]
- C. Did unmonitored individuals' activities change during the year which could put them over 10% of limit?
- D. If yes to C above, was a new evaluation performed?

- E. Is external dosimetry provided to individuals as required by **12VAC5-481-760** and **12VAC5-481-2850** and to individuals likely to receive >10% of limit?
1. Irradiator Operators: Is the dosimetry supplier NVLAP approved? [**12VAC5-481-750**]
 2. Are the dosimeters exchanged monthly for film badges and quarterly for OSLs?
 3. Are dosimetry reports reviewed by the RSO upon receipt?
 4. Are dosimeters provided to persons who enter the radiation room of a panoramic irradiator? [**12VAC5-481-2850**]
 5. Annual checks of accuracy of pocket dosimeters performed? [**12VAC5-481-2850**]
 6. Are the records VDH Forms or equivalent? [**12VAC5-481-1020, 12VAC5-481-1040**]
 - a. VDH Form "Cumulative Occupational Exposure History" completed?
 - b. VDH Form "Occupational Exposure Record for a Monitoring Period" completed?
 7. Declared pregnant worker/embryo/fetus
 - a. If a worker declared her pregnancy, did licensee comply with **12VAC5-481-710**?
 - b. Were records kept of embryo/fetus dose per **12VAC5-481-1040**?
- F. Are records of exposures, surveys, monitoring, and evaluations maintained [**12VAC5-481-990, 12VAC5-481-1000, 12VAC5-481-1040, and 12VAC5-481-2930**]

Public Dose

- A. Is public access controlled in a manner to keep doses below 1 mSv (100 mrem) in a year? [**12VAC5-481-720**]
- B. Has a survey or evaluation been performed per **12VAC5-481-730**? Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?
- C. Do unrestricted area radiation levels exceed 0.02 mSv (2 mrem) in any one hour? [**12VAC5-481-720**]
- D. Is access to sealed sources controlled in a manner that would prevent unauthorized use or removal? [**12VAC5-481-840**]
- E. Records maintained? [**12VAC5-481-1050**]

Operating And Emergency Procedures

- A. Have operating and emergency procedures been developed? [**12VAC5-481-2840**]
- B. Do they contain the required elements?
- C. Does each individual working with the sealed sources have a current copy of the operating and emergency procedures (including emergency telephone numbers)?

D. 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, 12VAC5-481-1150, 12VAC5-481-2940]

Leak Tests

A. Were sealed sources leak tested at prescribed intervals? [12VAC5-481-740 and 12VAC5-481-2870]

B. Was the leak test performed according to regulatory requirements? [12VAC5-481-740 and 12VAC5-481-2870]

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

D. Were any sealed sources found leaking and if yes, were appropriate actions taken and was VDH notified? [12VAC5-481-740, 12VAC5-481-1150, 12VAC5-481-2870, 12VAC5-481-2940]

Inspection and Maintenance Checks

A. Are all procedures for maintenance of the irradiator being followed where applicable?

B. Are all checks to determine proper functioning and wear of the source movement systems performed at frequencies as specified in the license application?

C. Are labels, signs, and postings clean and legible?

D. Are checks for operability as required by 12VAC5-481-2880 (not included in item 4) performed at frequencies and according to procedures described in license application:

1. Each aspect of the access control system
2. Emergency source return control
3. Heat/smoke detectors, extinguisher system
4. Pool water replacement system high and low water indicators
5. For underwater irradiators, was the intrusion alarm tested for operability? (Frequency of checks as specified in license application?)

E. Are checks for functioning and condition of equipment performed at required frequencies and according to procedures described in license application:

1. Assessment of the condition and operability of the source rack protector are performed at the required frequencies [12VAC5-481-2880]?
2. Assessment of water added to the pool to determine if there is pool leakage are performed at required frequencies as required by 12VAC5-481-2880?

3. Assessment of radiation damage to electrical wiring are performed at required frequencies as required by **12VAC5-481-2880**?
4. Water conductivity and analysis are performed at required frequencies? [**12VAC5-481-2890**]
5. Confirmation that water circulation system is leak tight? [**12VAC5-481-2880**]
6. Functioning of the source position indicator? [**12VAC5-481-2880**]
7. Leak tightness of water circulation system, visual inspection? [**12VAC5-481-2880**]

Repair and Preventive Maintenance

- A. Are repair and maintenance of components related to the radiological safety of the irradiator performed by the manufacturer or person specifically authorized by the VDH, NRC, or another Agreement State and according to license requirements (e.g., extent of work, procedures, dosimetry, survey instrument, compliance with **12VAC5-481-720** limits)?
- B. Malfunctions and defects found during inspection and maintenance checks are repaired without undue delay.

Transportation

Note: This section will not apply if you have not transported sealed sources during the period covered by this audit.

- A. Were sources shipped since the last audit?
- B. If so, were **12VAC5-481 'Virginia Radiation Protection Regulations', Part XIII, 'Transportation of Radioactive Material'** requirements followed?
- C. DOT-Type A or Type B packages used? [**12VAC5-481 'Virginia Radiation Protection Regulations', Part XIII, 'Transportation of Radioactive Material', 49 CFR 173.415, 49 CFR 173.416(b)**] If Type B, VDH Certificate of Compliance granted before shipment or shipper is registered as a user of the Type B package? VDH approved QA program?
- D. Package performance test records on file? [**49 CFR 173.415(a)**]
- E. Special form sources documentation? [**49 CFR 173.476(a)**]
- F. Package has 2 labels (ex. Yellow-II) with TI, Nuclide, Activity, and Hazard Class? [**49 CFR 172.403, 49 CFR 173.441**]
- G. Package properly marked? [**49 CFR 172.301, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324**]
- H. Package closed and sealed during transport? [**49 CFR 173.475(f)**]

- I. Shipping papers prepared, used, and maintained? [49 CFR 172.200(a)]
- J. Shipping papers contain proper entries? {Shipping name, Hazard Class, Identification Number (UN Number), Total Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, Cargo Aircraft Only (if applicable)} [49 CFR 172.200, 49 CFR 172.201, 49 CFR 172.202, 49 CFR 172.203, 49 CFR 172.204, 49 CFR 172.604]
- K. Secured against movement? [49 CFR 177. 834]
- L. Placarded on vehicle, if needed? [49 CFR 172.504]
- M. Proper overpacks, if used? [49 CFR 173.25]
- N. Any incidents reported to DOT? [49 CFR 171.15, 49 CFR 171.16]

Auditor's Independent Survey Measurements

- A. Describe the type, location, and results of measurements. Does any radiation level exceed regulatory limits [12VAC5-481-640, 12VAC5-481-720 and 12VAC5-481-2860]?

Notification and Reports

- A. Was a telephone report made within 24 hours as described in 12VAC5-481-2940 and 12VAC5-481-1100, and a written report within 30 days as described in 12VAC5-481-1100 of any of the following:
1. Source stuck in an unshielded position
 2. Any fire or explosion in a radiation room
 3. Damage to the source rack
 4. Failure of the cable or drive mechanism used to move the source racks
 5. Inoperability of the access control system
 6. Detection of radioactive contamination attributable to licensed radioactive material
 7. Structural damage to the pool liner or walls
 8. Abnormal water loss or leakage from the source storage pool
 9. Pool water conductivity exceeding 100 microsiemens per centimeter.
- B. Was any radioactive material lost or stolen? Were reports made? [12VAC5-481-1090]
- C. Did any reportable incidents occur? Were reports made? [12VAC5-481-1100]
- D. Did any overexposures and high radiation levels occur? Reported? [12VAC5-481-1100, 12VAC5-481-1110]
- E. If any events (as described in items a through c above) did occur, what was root cause? Were corrective actions appropriate?

- F. Is the management/RSO/shift foreman licensee aware of telephone number for VDH Emergency Operations Center? [(804)864-8150, after hours (804) 674-2400 & (800) 468-8992 during normal business hours]

Posting and Labeling

- A. VDH Form "Notice to Workers" posted? [12VAC5-481-2260]
- B. VDH regulations, license documents posted or a notice posted? [12VAC5-481-2260]
- C. Other posting and labeling?

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?

Bulletins And Information Notices

- A. VDH and NRC Bulletins, VDH and NRC Information Notices, NMSS Newsletters, received?
- B. Appropriate training and action taken in response?

Special License Conditions or Issues

- A. Did auditor review special license conditions or other issues (e.g., non-routine operations)?

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. Are corrective actions planned or taken at ALL licensed locations (not just location audited)? 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 Radiation Safety Officer (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 L:
**Model Survey Instrument Calibration
Program**

Model Survey Instrument Calibration Program

Training

Before calibrating survey instruments independently, the individual should complete both classroom and on-the-job training as follows:

- Classroom training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:
 - Principles and practices of radiation protection
 - Radioactivity measurements, monitoring techniques, and the use of instruments
 - Mathematics and calculations basic to using and measuring radioactivity
 - Biological effects of radiation.
- On-the-job-training will be considered complete if the individual has:
 - Observed authorized personnel performing survey instrument calibration, and
 - Conducted survey meter calibrations under the supervision, and in the physical presence of an individual already authorized to perform calibrations.

Facilities and Equipment

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

Model Procedure for Calibrating Survey Instruments

1. A radioactive sealed source(s) will be used for calibrating survey instruments, and this source will:
 - Approximate a point source
 - Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified to be within $\pm 5\%$ accuracy by National Institutes of Standards and Technology (NIST)
 - Contain a radionuclide which emits photons of identical or similar energy as the sealed sources that the instrument will measure
 - Be strong enough to give an exposure rate of at least 30 mR/hour (7.7 microcoulomb/kilogram per hour) at 100 cm [e.g., 3.1 gigabecquerels (85 millicuries) of Cs-137 or 780 megabecquerels (21 millicuries) of Co-60].
2. Inverse square and radioactive decay laws must be used to correct changes in exposure rate due to changes in distance or source decay.
3. A record must be made of each survey meter calibration.

4. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than $\pm 20\%$.
5. There are three kinds of scales frequently used on radiation survey meters. They are calibrated as follows:
 - Meters on which the user selects a linear scale must be calibrated at not fewer than two points on each scale. The points will be at approximately $1/3$ and $2/3$ of the decade.
 - Meters that have a multidecade logarithmic scale must be calibrated at one point (at the least) on each decade and not fewer than two points on one of the decades. Those points will be approximately $1/3$ and $2/3$ of the decade.
 - Meters that have an automatically ranging digital display device for indicating exposure rates must be calibrated at one point (at the least) on each decade and at no fewer than two points on one of the decades. Those points should be at approximately $1/3$ and $2/3$ of the decade.
6. Readings above 200 mR/hour (50 microcoulomb/kilogram per hour) need not be calibrated. However, higher scales should be checked for operation and approximately correct response.
7. Survey meter calibration reports will indicate the procedure used and the results of the calibration. The reports will include:
 - The owner or user of the instrument
 - A description of the instrument that includes 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 on a specified date, and the calibration procedure
 - For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument
 - The exposure reading indicated with the instrument in the "battery check" mode (if available on the instrument)
 - For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)
 - For instruments with internal detectors, the angle between 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 from a check source, if used
 - The signature of the individual who performed the calibration and the date on which the calibration was performed.
8. The following information will be attached to the instrument as a calibration sticker or tag:
 - The source that was used to calibrate the instrument
 - The proper deflection in the battery check mode (unless this is clearly indicated on the instrument)
 - For each scale or decade not calibrated, an indication that the scale or decade was checked only for function but not calibrated
 - The date of calibration and the next calibration due date
 - The apparent exposure rate from the check source, if used.

References: Detailed information about survey instrument calibration may be obtained by referring to ANSI N323-1978, "Radiation Protection Instrumentation Test and Calibration." Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018 or ordered electronically at the following address: <<http://www.ansi.org>>. Draft Regulatory Guide FC 413-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments," dated June 1985.

Appendix M:

**Guidance for Demonstrating that
Unmonitored Individuals are Not Likely
to Exceed 10 Percent of the Allowable
Limits**

Guidance for Demonstrating that Unmonitored Individuals are Not Likely to Exceed 10 Percent of the Allowable Limits

Dosimetry is required for individuals likely to receive, in 1 year from sources external to the body, a dose in excess of 10% of the applicable regulatory limits in 12VAC5-481-640. However, irradiator operators are required by 12VAC5-481-2850 to wear either a film badge or an optically stimulated luminescence dosimeters (OSL) while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. Also, other individuals who enter the radiation room of a panoramic irradiator must wear a dosimeter, which may be a pocket dosimeter. When groups of visitors enter the radiation room at least two people must wear dosimeters. In those instances where pocket chambers are used instead of film badges or OSLs, a check of the response of the dosimeters to radiation must be made at least annually. Acceptable dosimeters must read within plus or minus 30% of the true radiation dose. To demonstrate that dosimetry is not required for other workers, a licensee needs to have available, for inspection, an evaluation to demonstrate that its workers are not likely to exceed 10% of the applicable annual limits.

The most common way that individuals might exceed 10% of the applicable limits is by performing work near the irradiator shield or areas of cable or equipment penetration of the shield of the irradiator. However, for most irradiators even these activities result in the individual receiving minimal doses. A licensee will need to evaluate the doses which its workers might receive in performing these tasks to assess whether dosimetry is required. The evaluation may be done by carefully measuring the dose rates when the source is in the irradiate position using techniques similar to those as described in Appendix N. An evaluation of the actual time workers spend in the area can provide the information needed to estimate the annual dose of the workers. The applicable TEDE (whole body) limit is 50 mSv (5 rems) per year and 10% of that value is 5 mSv (500 millirems) per year.

Example: A careful measurement of the highest dose rate at the face of the shield of a panoramic irradiator is found to be 0.015 mSv/hr (1.5 mrem/hr). An individual is expected to spend no more than 3 hours per week in the area near the shield. Based on the dose rate, assuming the source is continuously in the irradiate position while the work is being performed, the annual dose is expected to be less than 2.34 mSv (234 mrem) (i.e., 3 hr/wk x 1.5 mrem/hr x 52 wk/yr). Based on the above specific information, no dosimetry is required if the individual performs work in the area less than 6.4 hours per week.

Appendix N:

**Guidance for Demonstrating That
Individual Members of the Public Will
Not Receive Doses Exceeding the
Allowable Limits**

Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

Licensees must ensure that:

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

Members of the public include persons who live, work, or may be near locations where an irradiator is used or where the sealed sources for the irradiator are stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where irradiators are used or sources stored.

- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.

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

Licensees must show compliance with both portions of the regulation. For areas around irradiator facilities, a combination of calculations and measurements (e.g., using an environmental TLD) is often used to prove compliance.

Combined Measurement - Calculation Method

These measurements must be made with calibrated survey meters sufficiently sensitive to measure background levels of radiation. However, licensees must exercise caution when making these measurements and they must use currently calibrated radiation survey instruments. A maximum dose of 1 mSv (100 mrem) received by an individual over a period of 2080 hours (i.e., a "work year" of 40 hr/wk for 52 wk/yr) is equal to less than 0.5 microsievert (0.05 mrem) per hour.

This rate is well below the minimum sensitivity of most commonly available GM survey instruments. TLDs used for personnel monitoring (e.g., LiF) may not have sufficient sensitivity for this purpose. Generally, the minimum reportable dose received is 0.1 mSv (10 mrem). Suppose a TLD monitors dose received and is changed once a month. If the measurements are at the minimum reportable level, the annual dose received could have been about 1.2 mSv (120 mrem), a value in excess of the 1 mSv/yr (100 mrem/yr) limit. If licensees use TLDs to evaluate compliance with the public dose limits, they should consult with their TLD supplier and choose more sensitive TLDs, such as those containing CaF_2 that are used for environmental monitoring.

Instruments used to make measurements for calculations must be sufficiently sensitive. An instrument equipped with a scintillation type detector (e.g., NaI(Tl)) or a micro-R meter used in making very low gamma radiation measurements should be adequate.

Licenseses may also choose to use environmental TLDs in unrestricted areas next to the irradiator area for monitoring. This direct measurement method would provide a definitive measurement of actual radiation levels in unrestricted areas without any restrictive assumptions. Records of these measurements can then be evaluated to ensure that rates in unrestricted areas do not exceed the 1 mSv/yr (100 mrem/yr) limit.

The combined measurement-calculation method may be used to estimate the maximum dose to a member of the public. Since irradiators are designed so that the maximum dose rate in any public area is less than 0.02 mSv (2 mrem) in any one hour, the licensee will generally be able to show by calculation that the maximum dose to an individual will be less than the 1 mSv/yr (100 mrem/yr) limit. The combined measurement-calculation method takes a tiered approach, going through a two-part process starting with a worst case situation and moving toward more realistic situations. It makes the following simplifications: (1) each irradiator is a point source; (2) typical radiation levels encountered when the source is in the unshielded position; and (3) no credit is taken for any shielding found between the irradiator shield and the unrestricted areas. The method is only valid for the source activity at the time of measurement and must be repeated if the source strength or shielding is changed.

Even though most large irradiators approximate a planar source, the results obtained from a point source assumption will be conservative and therefore may be used. Part 1 of the combined measurement-calculation method is simple but conservative. It assumes that an affected member of the public is present 24 hours a day and uses only the inverse square law to determine if the distance between the irradiator and the affected member of the public is sufficient to show compliance with the public dose limits. Part 2 considers not only distance, but also the time that the affected member of the public is actually in the area under consideration. Using this approach, licenseses make only those calculations that are needed to demonstrate compliance. The results of these calculations typically result in higher radiation levels than would exist at typical facilities, but provide a method for estimating conservative doses which could be received.

Example

To better understand the combined measurement-calculation method, we will examine Food-Safe, Inc., an irradiator licensee. Yesterday, the company's president noted that the shield of the new irradiator area is close to an area used by workers whose assigned duties do not include the use of licensed materials and he asked Leslie, the Radiation Safety Officer (RSO), to determine if the company is complying with VDH's regulations.

The area in question is near the wall which constitutes the primary shield of the irradiator. Leslie measures the distance from the shield to the center of the area in question and, using a calibrated survey instrument, measures the highest dose rate at one foot from the shield, to be 2 mrem per hour. **Table 7** summarizes the information Leslie has on the irradiator.

Table 7: Information Known About Dose at the Shield of the Irradiator

Description of Known Information	Co-60 Panoramic Irradiator
Dose rate encountered at 1 foot from the face of the shield, in mrem/hr.	2 mrem/hr.
Distance from the face of the shield to the nearest occupied work area, in ft.	4 ft

Example: Part 1

Leslie’s first thought is that the distance between the irradiator shield and the area in question may be sufficient to show compliance with the regulation in **12VAC5-481-720**. So, taking a worst case approach, she assumes: 1) the irradiator is constantly in use (i.e., 24 hr/d), and 2) the workers are constantly in the unrestricted work area (i.e., 24 hr/d). Leslie proceeds to calculate the dose the workers might receive hourly and yearly from the irradiator as shown in **Table 8** below.

Table 8: Calculation Method, Part 1: Hourly and Annual Dose Received from Irradiator

Step No.	Description	Input Data	Results
1	Multiply the measured dose rate measured at 1.0 ft from the face of the shield wall in mrem/hr by the square of the distance (ft) at which the measurement was made (e.g., 1 foot from the face of the shield)	$2 \times (1)^2$	2
2	Square of the distance (ft) from the face of the shield to the nearest unrestricted area, in ft^2	$(4)^2$	16
3	Divide the result of Step 1 by the result of Step 2 to calculate the dose received by an individual in the area near the shield. HOURLY DOSE RECEIVED FROM IRRADIATOR , in mrem in an hour	2/16	0.125
4	Multiply the result of Step 3 by 40 hr/work week x 52 weeks/year = MAXIMUM ANNUAL DOSE RECEIVED FROM IRRADIATOR , in mrem in a year	$0.125 \times 40 \times 52$	260

Note: The result in Step 3 demonstrates compliance with the 2 mrem in any one hour limit. Reevaluate if assumptions change. If the result in Step 4 exceeds 100 mrem/yr, proceed to Part 2 of the calculation method.

At this point, Leslie is pleased to see that the total dose that an individual could receive in any one hour is only 0.125 mrem in an hour, less than the 2 mrem in any one hour limit but notes that an individual could receive a dose of 260 mrem in a year, higher than the 100 mrem limit.

Example: Part 2

Leslie reviews the assumptions and recognizes that the workers are not in area near the shield all of the time. A realistic estimate of the number of hours the workers spend in the area is made, keeping the other assumptions constant (i.e., the irradiator is in constant use (i.e., 24 hr/d). The annual dose received is then recalculated.

Table 9: Calculation Method, Part 2: Annual Dose Received from an Irradiator

Step No.	Description	Results
5	A. Average number of hours per day an individual spends in area of concern (e.g., a non-radiation worker spends 1.5 hr/day in the area near the shield; the remainder of the day the workers are away from the area assigned to jobs unrelated to radiation. (painting, grounds keeping, desk jobs, etc.)	1.5
	B. Average number of days per week in area	5
	C. Average number of weeks per year in area (e.g., full time workers)	52
6	Multiply the results of Step 5.A. by the results of Step 5.B. by the results of Step 5.C. = AVERAGE NUMBER OF HOURS IN AREA OF CONCERN PER YEAR	$1.5 \times 5 \times 52 = 390$
7	Multiply the results in Step 3 by the results of Step 6 = ANNUAL DOSE RECEIVED FROM IRRADIATOR CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN, in mrem in a year	$0.125 \times 390 = 49$

Leslie is pleased to note that the calculated annual dose received is significantly lower, and does not exceed the 100 mrem in a year limit. Since most irradiators are in use a majority of the time, and down time is usually unpredictable, generally no additional allowance for irradiator duty cycle is made. Leslie is glad to see that the results in Step 7 show compliance with the 100 mrem in a year limit. Had the result in Step 7 been higher than 100 mrem in a year, then Leslie could have done one or more of the following:

- Consider whether the assumptions used to determine occupancy are accurate, revise the assumptions as needed, and recalculate using the new assumptions
- Calculate the effect of any shielding located between the irradiator shield and the public area (such calculation is beyond the scope of this Appendix)
- Take corrective action (e.g., change work patterns to reduce the time spent in the area near the shield) and perform new calculations to demonstrate compliance
- Designate the area inside the use area as a restricted area and the workers as occupationally exposed individuals. This would require controlling access to the area for purposes of radiation protection and training the workers as required by 12VAC5-481-2270

Note that in the example, Leslie evaluated the unrestricted area outside only one wall of the irradiator area. Licensees also need to make similar evaluations for other unrestricted areas and to keep in mind the ALARA principal, taking reasonable steps to keep radiation dose received below regulatory requirements. In addition, licensees need to be alert to changes in situations (e.g., adding sources to the irradiator, changing the work habits of the workers, or otherwise changing the estimate of the portion of time spent in the area in question) and to perform additional evaluations, as needed.

RECORDKEEPING: 12VAC5-481-1050 requires licensees to maintain records demonstrating compliance with the dose limits for individual members of the public.

Appendix O:

**Typical VDH Incident Notifications
Required for Irradiator Licensees**

Table 10: Typical VDH Incident Notifications Required for Irradiator 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
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	Immediate	30 days	12VAC5-481-1100
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	12VAC5-481-1100
Whole body dose greater than 1 mSv (100 rems)	None	30 days	12VAC5-481-1110
Dose to individual member of public greater than 1 mSv (100 mrems)	none	30 days	12VAC5-481-1110
Defect in equipment that could create a substantial safety hazard	2 days	30 days	12VAC5-481-1110, 12VAC5-481-2940, 10 CRF 21
Event that prevents immediate protection actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	Immediate	30 days	12VAC5-481-1110
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	12VAC5-481-1110
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	12VAC5-481-1110
Source stuck in an unshielded position	24 hours	30 days	12VAC5-481-2940
Any fire or explosion in a radiation room	24 hours	30 days	12VAC5-481-2940
Damage to the source racks	24 hours	30 days	12VAC5-481-2940

Event	Telephone Notification	Written Report	Regulatory Requirement
Failure of the cable or drive mechanism used to move the source racks	24 hours	30 days	12VAC5-481-2940
Inoperability of the access control system	24 hours	30 days	12VAC5-481-2940
Detection of radiation source by the product exit monitor	24 hours	30 days	12VAC5-481-2940
Detection of radioactive contamination attributable to licensed radioactive material	24 hours	30 days	12VAC5-481-2940
Structural damage to the pool liner or walls	24 hours	30 days	12VAC5-481-2940
Abnormal water loss or leakage from the source storage pool	24 hours	30 days	12VAC5-481-2940
Pool water conductivity exceeding 100 microsiemens per centimeter	24 hours	30 days	12VAC5-481-2940

Note: Telephone notifications shall be made to VDH at (804) 864-8150 or after hours at (804) 74-2400 or (800) 468-8992, except as noted.

Appendix P:

Model Leak Test Program For Dry-Source-Storage Irradiator Sealed Sources

Model Leak Test Program For Dry-Source-Storage Irradiator Sealed Sources

Training

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

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

- Principles and practices of radiation protection
- Radioactivity measurements, monitoring techniques, and the use of instruments
- Mathematics and calculations basic to the use and measurement of radioactivity
- Biological effects of radiation.

Appropriate on-the-job-training consists of:

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

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests will be analyzed in a low-background area.
- Individuals conducting leak tests will use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed.
- A NaI(Tl) well counter system with a single or multichannel analyzer will be used to count samples from sealed sources containing gamma-emitters (e.g., Cs-137, Co-60).
- Frequency for conducting leak tests of sealed sources per Sealed Source and Device registration or leak tests will be conducted at least every 6 months.

Model Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as 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. Prepare one swipe per irradiator, if more than one source is contained in the same enclosure.
- 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 200 becquerels (0.005 microcurie).
- Using the selected instrument, count and record background count rate.
- Check the instrument's counting efficiency using standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within $\pm 5\%$ of the stated value and traceable to a primary radiation standard such as those maintained by the National Institutes of Standards and Technology (NIST).
- Calculate efficiency.
For example:
$$\frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of std in Bq}} = \text{efficiency in cpm/Bq}$$
 - where: cpm = counts per minute
 - std = standard
 - bkg = background
 - Bq = Becquerel
- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in becquerels (or microcuries).
For example:
$$\frac{[(\text{cpm from wipe sample}) - (\text{cpm from bkg})]}{\text{efficiency in cpm/Bq}} = \text{Bq on wipe sample}$$
- Sign and date the list of sources, data, and calculations. Retain records for 3 years.
- If the wipe test activity is 200 becquerels (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 Q:
Transportation

Transportation

Major DOT Regulations

The major areas in the DOT regulations that are most relevant for transportation of licensed materials used in Irradiators are as follows:

- Table of Hazardous Materials and Special Provisions **49 CFR 172.101**, and App. A, Table 2: Hazardous materials table, list of hazardous substances and reportable quantities
- Shipping Papers **49 CFR 172.200-204**: general entries, description, additional description requirements, shipper's certification
- Package Markings **49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324**: General marking requirements for non-bulk packaging, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging
- Package Labeling **49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440**: General labeling requirements, prohibited labeling, radioactive materials, placement of labels, specifications for radioactive labels
- Placarding of Vehicles **49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556**: Applicability, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, RADIOACTIVE placard
- Emergency Response Information, Subpart G, **49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604**: Applicability and general requirements, emergency response information, emergency response telephone number
- Training, Subpart H, **49 CFR 172.702, 49 CFR 172.704**: Applicability and responsibility for training and testing, training requirements
- Radiation Protection Program for Shippers and Carriers, Subpart I, **49 CFR 172.800**, etc.
- Shippers - General Requirements for Shipments and Packaging, Subpart I, **49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.411, 49 CFR 173.412, 49 CFR 173.413, 49 CFR 173.415, 49 CFR 173.416, 49 CFR 173.415, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.471, 49 CFR 173.475, 49 CFR 173.476**: Definitions, general design requirements, industrial packages, additional design requirements for Type A packages, requirements for Type B packages, authorized Type A packages, authorized Type B packages (including package certification requirements), requirement for determining A1 and A2..., table of A1 and A2 values for radionuclides, radiation level limit, requirements for VDH approved packages (Type B), quality control requirements prior to each shipment..., approval of special form radioactive materials
- Carriage by Public Highway **49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842**: Driver training, shipping paper, general requirements (secured against movement), Class 7 (radioactive) material.

Hazard Communications for Class 7 (Radioactive) Materials

DOT Shipping Papers (49 CFR 172.200-205)

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

Entries Always Required Unless Excepted	Additional Entries Sometimes Required	Optional Entries
<ul style="list-style-type: none"> • The basic description, in sequence: Proper Shipping Name, Hazard Class (7), U.N. Identification Number • 24 hour emergency response telephone number • Name of shipper • Proper page numbering (Page 1 of 4) • Except for empty and bulk packages, the total quantity (mass, or volume for liquid), in appropriate units (lbs, mL,....) • If not special form, chemical and physical form • The name of each radionuclide (95 percent rule) and total package activity. The activity must be in SI units (e.g., Bq, TBq), or both SI units and customary units (e.g., Ci, mCi). However, for domestic shipments, the activity may be expressed in terms of customary units only, until 4/1/97. • For each labeled package: <ul style="list-style-type: none"> - The category of label used; - The transport index of each package with a Yellow-II or Yellow-III label - Shipper's certification (not required of private carriers) 	<p>Materials-Based Requirements</p> <ul style="list-style-type: none"> • If hazardous substance, "RQ" as part of the basic description • The LSA or SCO group (e.g., LSA-II) • "Highway Route Controlled Quantity" as part of the basic description, if HRCQ • Fissile material information (e.g., "Fissile Exempt," controlled shipment statement [see §172.203(d)(7)]) • If the material is considered hazardous waste and the word waste does not appear in the shipping name, then "waste" must precede the shipping name (e.g., Waste Radioactive Material, nos, UN2982) • "Radioactive Material" if not in proper shipping name <p>Package-Based Requirements</p> <ul style="list-style-type: none"> • Package identification for DOT Type B or NRC certified packages • IAEA CoC ID number for export shipments or shipments using foreign-made packaging (see §173.473) <p>Administrative-Based Requirements</p> <ul style="list-style-type: none"> • "Exclusive Use-Shipment" • Instructions for maintenance of exclusive use-shipment controls for LSA/SCO strong-light or NRC certified LSA (§ 173.427) • If a DOT exemption is being used, "DOT-E" followed by the exemption number 	<ul style="list-style-type: none"> • The type of packaging (e.g., Type A, Type B, IP-1,) • The technical/chemical name may be included (if listed in §172.203(k), in parentheses between the proper shipping name and hazard class; otherwise inserted in parenthesis after the basic description) • Other information is permitted (e.g., functional description of the product), provided it does not confuse or detract from the proper shipping name or other required information • For fissile radionuclides, except Pu-238, Pu-239, and Pu-241, the weight in grams or kilograms may be used in place of activity units. For Pu-238, Pu-239, and Pu-241, the weight in grams or kilograms may optionally be entered in addition to activity units [see §172.203(d)(4)] • Emergency response hazards and guidance information (§§172.600-604) may be entered on the shipping papers, or may be carried with the shipping papers [§172.602(b)]

Some Special Considerations/Exceptions for Shipping Paper Requirements

- Shipments of Radioactive Material, excepted packages, under UN2910 (e.g., Limited Quantity, Empty packages, and Radioactive Instrument and Article), are excepted from shipping papers. For limited quantities (§173.421), this is only true if the limited quantity is not a hazardous substance (RQ) or hazardous waste (40 CFR 262).
- Shipping papers must be in the pocket on the left door, or readily visible to a person entering the driver's compartment and within arm's reach of the driver.
- For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, be designated by an "X" (or "RQ") in the hazardous material column, or be highlighted in a contrasting color.

- A. The limits in this table do not apply to excepted packages - see 49 CFR 173.421-426.
- B. Securely attached (to vehicle), access-limiting enclosure; package personnel barriers are considered as enclosures.
- C. For nonfissile radioactive materials packages, the dimensionless number equivalent to maximum radiation level at 1 m (3.3 feet) from the exterior package surface, in millirem/hour.
- D. No dose limit is specified, but separation distances apply to Radioactive Yellow-II or Radioactive Yellow-III labeled packages.
- E. This does not apply to private carrier wearing dosimetry if under radiation protection program satisfying 10 CFR 20 or 49 CFR 172 Subpart I.
- F. Some fissile shipments may have combined conveyance TI limit of 100 - see 10 CFR 71.59 and 49 CFR 173.457.

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

Marking Packages (49 CFR 172.300-338)

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

Markings Always Required Unless Excepted	Additional Markings Sometimes Required	Optional Markings
<p>Non-Bulk Packages</p> <ul style="list-style-type: none"> • Proper shipping name • U.N. identification number • Name and address of consignor or consignee, <i>unless</i>: <ol style="list-style-type: none"> 1. highway only and no motor carrier transfers; or part of carload or truckload lot or freight container load, and entire contents of railcar, truck, or freight container are shipped from one consignor to one consignee [see §172.301(d)] <hr/> <p>Bulk Packages (i.e., net capacity greater than 119 gallons as a receptacle for liquid, or 119 gallons and 882 pounds as a receptacle for solid, or water capacity greater than 1000 lbs, with no consideration of intermediate forms of containment)</p> <ul style="list-style-type: none"> • U.N. identification number, on orange, rectangular panel (see §172.332) - some exceptions exist 	<p>Materials-Based Requirements</p> <ul style="list-style-type: none"> • If in excess of 110 lbs (50 kg), Gross Weight • If non-bulk <i>liquid</i> package, underlined double arrows indicating upright orientation (two opposite sides) [ISO Std 780-1985 marking] • If a Hazardous substance in non-bulk package, the letters "RQ" in association with the proper shipping name <div style="text-align: center; margin: 10px 0;">  </div> <p>Package-Based Requirements</p> <ul style="list-style-type: none"> • The package type if Type A or Type B (½" or greater letters) • The specification-required markings [e.g., for Spec. 7A packages: "DOT 7A Type A" and "Radioactive Material" (see §178.350-353)] • For approved packages, the certificate ID number (e.g., USA/9166/B(U), USA/9150/B(U)-85, ...) • If Type B, the trefoil (radiation) symbol per Part 172 App. B [size: outer radius ≥ 20 mm (0.8 in)] • For NRC certified packages, the model number, gross weight, and package ID number (10 CFR 71.85) <p>Administrative-Based Requirements</p> <ul style="list-style-type: none"> • If a DOT exemption is being used, "DOT-E" followed by the exemption number • If an export shipment, "USA" in conjunction with the specification markings or certificate markings 	<ul style="list-style-type: none"> • "IP-1," "IP-2," or "IP-3" on industrial packaging is recommended • Both the name and address of consignor and consignee are recommended • Other markings (e.g., advertising) are permitted, but must be sufficiently away from required markings and labeling

Some Special Considerations/Exceptions for Marking Requirements

- Marking is required to be: (1) durable, (2) printed on a package, label, tag, or sign, (3) unobscured by labels or attachments, (4) isolated from other marks, and (5) be representative of the hazmat contents of the package.
- Limited Quantity (§173.421) packages and Articles Containing Natural Uranium and Thorium (§173.426) must bear the marking "radioactive" on the outside of the inner package or the outer package itself, and are excepted from other marking. The excepted packages shipped under UN 2910 must also have the accompanying statement that is required by §173.422.
- Empty (§173.428) and Radioactive Instrument and Article (§173.424) packages are excepted from marking.
- Shipment of LSA or SCO required by §173.427 to be consigned as exclusive use are excepted from marking except that the exterior of each nonbulk package must be marked "Radioactive-LSA" or "Radioactive-SCO," as appropriate. Examples of this category are domestic, strong-tight containers with less than an A₂ quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52.
- For bulk packages, marking may be required on more than one side of the package (see 49 CFR 172.302(a)).

Some Special Considerations/Exceptions for Placarding Requirements

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

Hazard Communications for Class 7 (Radioactive) Materials

Placarding Vehicles (49 CFR 172.500-560)

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

Visibility and Display of Radioactive Placard

- Placards are required to be displayed:
 - On four sides of the vehicle;
 - Visible from the direction they face, (for the front side of trucks, tractor-front, trailer, or both are authorized);
 - Clear of appurtenances and devices (e.g., ladders, pipes, tarpaulins);
 - At least 3 inches from any markings (such as advertisements) which may reduce placard's effectiveness;
 - Upright and on-point such that the words read horizontally;
 - In contrast with the background, or have a lined-border which contrasts with the background;
 - Such that dirt or water from the transport vehicle's wheels will not strike them;
 - Securely attached or affixed to the vehicle, or in a holder.
- Placard must be maintained by carrier to keep color, legibility, and visibility.

Conditions Requiring Placarding

- Placards are required for any vehicle containing a package with a RADIOACTIVE Yellow-III label.
- Placards are required for shipment of LSA or SCO required by §173.427 to be consigned as exclusive use. Examples of this category are domestic, strong-tight containers with less than an A₂ quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52. Also, for bulk packages of these materials, the orange panel marking with the UN Identification number is not required.
- Placards are required for any vehicle containing a package with a Highway Route Controlled Quantity (HRCQ). In this case, the placard must be placed in a square background as shown below (see §173.507(a)).

Radioactive Placard

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

Package and Vehicle Contamination Limits (49 CFR 173.443)

This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials.

NOTE: All values for contamination in DOT rules are to be averaged over each 300 cm²
Sufficient measurements must be taken in the appropriate locations to yield representative assessments

6γ means the sum of beta emitters, gamma emitters, and low-toxicity alpha emitters
* means the sum of all other alpha emitters (i.e., other than low-toxicity alpha emitters)

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

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

Deviation from Basic Limits	Regulation 49 CFR §§	Applicable Location and Conditions Which must Be Met:
10 times the basic limits	173.443(b) and 173.443(c) Also see 177.843 (highway)	<p>On any external surface of a package in an exclusive use shipment, during transport including end of transport. Conditions include:</p> <ul style="list-style-type: none"> • Contamination levels at beginning of transport must be below the basic limits. • Vehicle must not be returned to service until radiation level is shown to be ≤ 0.005 mSv/hr (0.5 mrem/hr) at any accessible surface, and there is no significant removable (non-fixed) contamination.
10 times the basic limits	173.443(d) Also see 177.843 (highway)	<p>On any external surface of a package, at the beginning or end of transport, if a closed transport vehicle is used, solely for transporting radioactive materials packages. Conditions include:</p> <ul style="list-style-type: none"> • A survey of the interior surfaces of the empty vehicle must show that the radiation level at any point does not exceed 0.1 mSv/hr (10 mrem/hr) at the surface, or 0.02 mSv/hr (2 mrem/hr) at 1 meter (3.3 ft). • Exterior of vehicle must be conspicuously stenciled, "For Radioactive Materials Use Only" in letters at least 76 mm (3 inches) high, on both sides. • Vehicle must be kept closed except when loading and unloading.
100 times the basic limits	173.428	<p>Internal contamination limit for excepted package-empty packaging, Class 7 (Radioactive) Material, shipped in accordance with 49 CFR 173.428. Conditions include:</p> <ol style="list-style-type: none"> (1) The basic contamination limits (above) apply to external surfaces of package. (2) Radiation level must be ≤ 0.005 mSv/hr (0.5 mrem/hr) at any external surface. (3) Notice in § 173.422(a)(4) must accompany shipment. (4) Package is in unimpaired condition & securely closed to prevent leakage. (5) Labels are removed, obliterated, or covered, and the "empty" label (§172.450) is affixed to the package.

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

STRAIGHT BILL OF LADING

ORIGINAL - NOT NEGOTIABLE

Appendix K --

Shipper No. _____

Carrier No. _____

Page 1 of 1

(Name of carrier)

(SCAC)

Date _____

TO: Builders, Inc. ** <small>Consignee</small> <small>On Collect on Delivery shipments, the letters "COD" must appear before consignee's name or as otherwise provided in Item 430, Sec. 1.</small>	FROM: Moisture Density Measurements, Inc. ** <small>Shipper</small>
Street <u>5678 Jefferson Davis Highway **</u>	Street <u>1234 A Street, NW **</u>
Destination <u>Arlington, VA**</u> Zip Code <u>22222**</u>	City <u>Washington, DC 20000**</u>

No. of Units & Container Type	HM	BASIC DESCRIPTION <small>Proper Shipping Name, Hazard Class, Identification Number (UN or NA), per 172, 173, 177, 202, 172, 202</small>	TOTAL QUANTITY <small>(Weight, Volume, Gallons, etc.)</small>	WEIGHT <small>(Shipped to Consignee)</small>	RATE	CHARGES <small>(If for Carrier Use Only)</small>
1	RQ	Radioactive material, special form n.o.s. 7 UN2974 0.41GBq (11 mCi) Cs-137 and 1.9GBq (50 mCi) Am-241:Be RADIOACTIVE - YELLOW II TI = 0.4 ** USDOT 7A TYPE A Emergency Response Telephone No.: 1-800-000-0000 (24 hr/d)**	2.31 GBq (61 mCi)			
		** SUBSTITUTE APPROPRIATE INFORMATION FOR YOUR GAUGE AND YOUR SHIPMENT				

PLACARDS TENDERED: YES NO REMIT C.O.D. TO ADDRESS

Note -- Where the rate is dependent on weight, shippers are required to state specifically in writing the agreed or declared value of the property. The agreed or declared value of the property is hereby specifically stated by the shipper to be not exceeding _____	I hereby declare that the contents of the transportation are fully and accurately described above by proper shipping name and are classified, packaged, marked and labeled, and are in all respects in proper condition for transport by a rail-transportation carrier under the provisions of the DOT'S OF TRANSPORT according to applicable international and national governmental regulations. <i>John James</i> Signature	COD AMT: \$ _____ Subject to Section 7 of the conditions, if this shipment is to be delivered to the consignee without recourse on this collection, the shipper shall sign the following statement: The consignor shall not make delivery of this shipment without payment of freight and all other lawful charges.	C.O.D. FEE: PREPAID <input type="checkbox"/> COLLECT <input type="checkbox"/> \$ _____ TOTAL CHARGES: \$ _____ FREIGHT CHARGES: _____ <small>Check for a proper amount when the bill is received.</small>
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RECEIVED, subject to the conditions and liability stated herein, on the date of the date of this Bill of Lading, the party described above at apparent good order, except as noted (specimen and condition of contents of packages unknown, marked, cartoned, and otherwise as indicated above which shall remain the sole responsibility of the shipper) the carrier hereby undertakes to transport the property as presented in possession of the party whose the contract herein is to carry it to the place of delivery at the destination if on its route, otherwise to deliver to another carrier on the route to said destination. It is hereby agreed as to each carrier of or by or, that liability over all of the property of

SHIPPER	CARRIER
PER	PER
	DATE

1

Appendix R:

**Exemptions for Teletherapy Units
Converted to Non-Human Use**

Exemptions for Teletherapy Units Converted to Non-Human Use

The following are technical justifications and commitments which are acceptable to exempt licensees from specific sections of **12VAC5-481 'Virginia Radiation Protection Regulations', Part XII, 'Licensing and Radiation Safety Requirements for Irradiators'**. Acceptable license conditions are also shown below.

1. **12VAC5-481-2730** - *"The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources."*

For converted teletherapy units, the use of a single key or even several keys on a key-ring may be impractical. The key-switch on many control panels is a 3-position switch which controls electrical power to the teletherapy unit. The key can only be inserted/removed in the "off" position, and in this position the main power and control circuits are without electrical power. Power is required to move collimators, activate field lights, align system, etc. Requiring a single key would not allow the licensee to operate these powered systems. Therefore, a licensee may be exempted from this requirement, provided that the licensee commits to have the operator present for the entire period of time that the key is in the control panel.

The following license condition should be used:

*"Notwithstanding the requirements of **12VAC5-481-2730**, the licensee may use separate keys to operate the lock on the personnel entrance door or barrier and to move the sources in accordance with procedures described in the letter/application dated ."*

2. **12VAC5-481-2730** - *"...each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while sources are exposed."*

The licensee may be granted an exemption from this requirement provided that the licensee has an electrical interlock system meeting all of the conditions specified in **12VAC5-481-2040** on each entrance to the radiation room. Alterations of the electrical interlocks of the teletherapy unit to meet the requirements of **12VAC5-481-2730** may cause the interlock system to function incorrectly. A working electrical interlock system on each entrance suffices to prevent personnel entry while the source is exposed. The licensee should commit in its application to each of the conditions of **12VAC5-481-2040**. In addition, the licensee should commit to having an operator present during the entire irradiation who can visually observe the entrance, and to having a radiation monitor that can be read before entering the radiation area.

The following license condition should be used:

*"Notwithstanding the requirements of **12VAC5-481-2730**, the licensee is exempt from having an independent backup access control to detect personnel entry while sources are exposed based on the commitments described in the letter/application dated."*

3. **12VAC5-481-2730** - *“...The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high.”*

Alteration of the interlock system to meet this requirement would prevent entry to the treatment room to remove a patient in the event of a stuck source. The VDH may grant the licensee an exemption from this requirement provided that the licensee has an electrical interlock system which will retract the source upon opening access doors to the radiation room and commits to its use. In addition, the licensee must commit to having an operator present and having a radiation monitor in the room as described above.

The following license condition should be used:

“Notwithstanding the requirements of **12VAC5-481-2730**, the licensee is exempt from having the monitor integrated with personnel access door locks to prevent room access when radiation levels are high based on the commitments described in the letter/application dated.”

4. **12VAC5-481-2730** - *“...visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position.”*

An acceptable justification is that an audible alarm within the treatment room may cause undue distress to the patients (human or animal). If the licensee commits to having a visual alarm provided on the outside of the treatment room and to having the operator visually check the room before starting treatments, VDH may grant the licensee an exemption.

The following license condition should be used:

“Notwithstanding the requirements of **12VAC5-481-2730**, the licensee is exempt from having an audible alarm within the treatment area, based on the commitments described in the letter/application dated.”

5. **12VAC5-481-2730** - *“Each radiation room at a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door...has been closed within a preset time...”*

Exemptions may be granted to licensees having teletherapy units that are being used for irradiation of materials only (no patients), provided that the licensee commits to the operator visually verifying that the room is not occupied before closing the door and that the converted teletherapy unit (irradiator) activates a visual and audible alarm in the teletherapy room for at least 15 seconds before moving the source from the shielded position. This visual/audible alarm must be interlocked with the teletherapy unit such that the source will not move to the exposed position until the visual/audible alarm has been activated and is finished alarming. The use of a visual/audible alarm in a patient treatment room may cause anxiety for patients. Therefore, licensees having teletherapy units that are being used for both patient treatment (human or animal) and object or material irradiation may be authorized an exemption from **12VAC5-481-2730** without the need to have a visual/audible alarm, if the licensee commits to having an operator visually verify that the room is not occupied before closing the door and if the licensee

has a means of visually observing the area as required in **12VAC5-481-2040**. If the unit is not used for patients, then the audible/visible alarm described above is required.

The following license condition should be used:

“Notwithstanding the requirements of **12VAC5-481-2730**, the licensee is exempt from having a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time based on the commitments described in the letter/application dated.”

6. **12VAC5-481-2750** - “...*The sources must automatically become shielded if a fire is detected.*”

12VAC5-481-2750 - “...be equipped with a fire extinguishing systems capable of extinguishing a fire without entry of personnel. The system must have a shutoff valve to control flooding into unrestricted areas.”

The Statements of Consideration state that the purpose of the fire extinguishing system is to prevent a fire from damaging the access control system or preventing the sources from being shielded. Most converted teletherapy units are designed to retract the source when the electrical power fails, as may occur during a fire. The licensee may be granted an exemption from these requirements provided that the licensee commits to the following:

- Having smoke detectors, fire extinguishers and a fire alarm at the site to detect and fight small fires
- Alerting authorities of the fire
- Having a means of measuring the radiation levels in the radiation room during an electrical failure
- Instructing the operators to retract the source before exiting for a fire involving major portions of the facility, provided this action does not jeopardize the operator’s safety.

The following license condition should be used:

“Notwithstanding the requirements of **12VAC5-481-2750**, the licensee is exempt from (as requested by the licensee) based on the commitments described in letter/application dated.”

7. **12VAC5-481-2770** - “*The key must be attached to a portable radiation survey meter by a chain or cable... The door to the radiation room must require the same key.*”

Converted teletherapy units require that the source activation key be inserted in the console to provide power to the unit to activate field lights and align the head. Therefore, VDH may grant the licensee an exemption from this requirement provided that the licensee commits to having administrative controls in place to ensure that personnel entering the radiation room use a portable survey meter to verify that the source has retracted. The licensee must also commit to attach the survey meter to the exposure room door key.

The following license condition should be used:

“Notwithstanding the requirements of **12VAC5-481-2770**, the licensee is exempt from the requirement to have console key attached to a portable survey meter by a chain or cable and that the door to the radiation room require the same key, based on the commitments described in the letter/application dated. The radiation room door key shall be attached to the portable survey meter.”

8. 12VAC5-481-2770 - “...*The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in...transit.*”

In converted teletherapy units the source is moved nearly instantaneously from the shielded to the exposed position. Most teletherapy units are designed with two indicator lights — green indicates the source is in the fully shielded position, red indicates the source is exposed. During transit, both lights are “on” indicating that the source is in transit. To require that the licensee install an electronic system to indicate “in transit” for the period of time the source is in transit, less than a second, does not provide any additional protection. Therefore, VDH may grant this exemption provided the licensee submits a description of its device indicators.

The following license condition should be used:

“Notwithstanding the requirements of **12VAC5-481-2770**, the licensee is exempt from the requirement to have a separate position indicator to indicate when the source is in transit, in accordance with letter/application dated.”

9. 12VAC5-481-2910 - “...*the irradiator operator...must activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.*”

Because of the risk of malfunction associated with alterations to the existing electrical interlocks of the teletherapy unit and considering the licensee’s commitment to administratively control access to the room to meet the intent of this regulation, VDH may grant this exemption if the licensee demonstrates that a retrofit to install such a control would not be possible with the teletherapy unit and a licensee commits to the following:

- The operator will close the doors immediately upon completion of the visual inspection required by **12VAC5-481-2910**.
- The operator will verify that each door has locked automatically before stepping to the control panel.

The following license condition should be used:

“Notwithstanding the requirements of **12VAC5-481-2910**, the licensee is exempt from the requirement to have a control in the radiation room which must be activated prior to irradiation which would not allow the source to be moved from the shielded position unless the door to the radiation room is locked within a preset time, based on the commitments described in the letter/application dated.”

Commonwealth of Virginia
Radiation Protection Regulatory Guide



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

EPI-720 F

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

EXECUTIVE SUMMARY

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

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

Requests for single copies of this guide (which may be reproduced) can be made in writing to Virginia Department of Health, Radiological Health Program, 109 Governor Street, Room 730, Richmond, VA 23219. This guide is also available on our website:

<http://www.vdh.virginia.gov/Epidemiology/RadiologicalHealth/>.

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

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

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

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

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

- Include any additional attachments.

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

Please identify all attachments with the applicant's name and license number (if a renewal).

- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original signed application along with attachments (if any).
- Submit the application fee (for new licenses only).
- Retain one copy of the license application and attachments (if any) for your future reference. You will need this information because the license will require that radioactive material be possessed and used in accordance with statements, representation, and procedures provided in the application and supporting documentation.

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

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ABBREVIATIONS

ALARA	as low as is reasonably achievable
ALI	annual limit on intake
bkg	background
Bq	Becquerel
CFR	Code of Federal Regulations
Ci	Curie
cc	centimeter cubed
cm ²	centimeter squared
Co-60	Cobalt-60
cpm	counts per minute
Cs-137	Cesium-137
DOT	United States Department of Transportation
dpm	disintegrations per minute
EDE	Effective dose equivalent
GM	Geiger-Mueller
IN	Information Notice
mCi	millicurie
mR	milliroentgen
mrem	millirem
mSv	millisievert
NIST	National Institute of Standards and Technology
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OSL	optically stimulated luminescence dosimeters
RG	Regulatory Guide
RSO	Radiation Safety Officer
SI	International System of Units (abbreviated SI from the French Le Système Internationale d'Unites)
SSDR	Sealed Source and Device Registration
Sv	Sievert
TEDE	total effective dose equivalent
TLD	thermoluminescent dosimeters
VDH	Virginia Department of Health
μCi	microcurie
%	percent

PURPOSE OF GUIDE

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

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

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

- **Rule** – references the requirements of 12VAC5-481 'Virginia Radiation Protection Regulations' applicable to the item;
- **Criteria** – outlines the criteria used to judge the adequacy of the applicant's response;
- **Discussion** – provides additional information on the topic sufficient to meet the needs of most readers; and
- **Response from Applicant** – shows the appropriate item on the application and provides: response(s), offers the option of an alternative response, or indicates that no response is needed on that topic.

The information submitted in the application must be sufficient to demonstrate that proposed equipment, facilities, personnel, and procedures are adequate to protect the health and safety of the citizens of the Commonwealth of Virginia in accordance with agency guidelines.

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

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

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

This VAREG provides the latest guidance and is modeled on the Nuclear Regulatory Commission's (NRC) NUREG 1556, Volume 11. The VAREG shows the requirements in terms of the **12VAC5-481 'Virginia Radiation Protection Regulation'** and provides a user-friendly format to assist with the preparation of an Academic, Research and Development, and other Licenses of Limited Scope license application.

LICENSES

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

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

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

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

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

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

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

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

WHO REGULATES FACILITIES IN THE COMMONWEALTH OF VIRGINIA?

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

Table 1: Who Regulates the Activity?

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

Note: 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 RESPONSIBILITIES

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

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

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

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

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

APPLICABLE RULE

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

The following parts of **12VAC5-481 'Virginia Radiation Protection Regulations'** contain requirements applicable to Academic, Research and Development, and other Licenses of Limited Scope licensees:

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

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

HOW TO FILE

Applicants for a materials license should do the following:

- Be sure to use the current guidance from VDH in preparing an application.
- Complete VDH Form, 'Application for Radioactive Material License Authorizing the Use of Radioactive Material for Academic Research and Development and other Licenses of Limited Scope' (**Appendix A**).
- For each separate sheet, other than submitted with the application, identify and key it to the item number on the application, or the topic to which it refers.
- Submit all documents on 8 ½ x 11 inch paper.
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original, signed application.
- Retain one copy of the license application for your future reference.

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

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

WHERE TO FILE

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

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

LICENSE FEES

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

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

Direct all questions about VDH's fees or completion of **Item 12** of VDH Form, 'Application for Radioactive Material License Authorizing the Use of Radioactive Material for Academic Research and Development and other Licenses of Limited Scope' (**Appendix A**) to: **Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, Virginia 23218** or **(804) 864-8150**.

CONTENTS OF APPLICATION

Item 1: Type of Application

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

Response from Applicant:

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

Item 2: Name and Mailing Address of Applicant

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

Response from Applicant:

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

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

Timely Notification of Change of Ownership or Control

Rule: 12VAC5-481-330, 12VAC5-481-500 B

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

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

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

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

Notification of Bankruptcy Proceedings

Rule: 12VAC5-481-500 E & F

Criteria: Immediately following filing of voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify VDH, in writing, identifying the bankruptcy court in which the petition was filed and the date of filing.

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

Item 3: Person to Contact Regarding Application

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

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

Response from Applicant:

<p>Item 3 Person To Contact Regarding Application:</p>
<p>Contact's Telephone Number (Include area code):</p> <p>() - x</p>

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

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

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

Discussion: Specify the street address, or other descriptive address (such as on Highway 58, 5 miles east of the intersection of Highway 58 and State Route 19), city and zip code for each permanent storage or use facility and field station. **A Post Office Box address is not acceptable** because the agency needs a specific address to allow a VDH inspector to find the use and/or storage location.

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

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

Response from Applicant:

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

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

Item 5: Radiation Safety Officer (RSO)

Rule: 12VAC5-481-450 A, 12VAC-481-630

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

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

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

- Radiation Protection Principles;
- Characteristics of Ionizing Radiation;
- Units of Radiation Dose and Quantities;
- Radiation Detection Instrumentation;
- Biological Hazards of Exposure to Radiation (appropriate to types and forms of radioactive material to be used);
- **12VAC5-481 'Virginia Radiation Protection Regulations'**; and
- Hands-on use of radioactive materials.

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

Response from Applicant:

<p>Item 5. Radiation Safety Officer (Check all that apply)</p> <p><input type="checkbox"/> The name of the proposed RSO who will be responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.</p> <p>Name: _____ Telephone Number (Include area code): () - x</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> Before obtaining radioactive materials, the proposed RSO will have successfully completed one of the training courses described in the section titled "Individual(s) Responsible for Radiation Safety Program and Their Training and Experience" in VAREG 'Guidance for Academic, Research and Development, and other Licenses of Limited Scope'.</p> <p style="text-align: center;">AND</p> <p>Before being named as the RSO, future RSOs will have successfully completed one of the training courses, described in the section titled "Individual(s) Responsible for the Radiation Safety Program and Their Training and Experience" in VAREG 'Guidance for Academic, Research and Development, and other Licenses of Limited Scope'.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> Alternative information demonstrating that the proposed RSO is qualified by training or experience.</p>
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Note: It is important to notify the agency, as soon as possible, of changes in the designation of the RSO. The name and qualifications of the replacement RSO must be submitted to the agency as part of an amendment request.

Item 6: Authorized Users & Training

Rule: 12VAC5-481-450 A, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-2260, 12VAC5-481-2270, 12VAC5-481-2280, 12VAC5-481-2310

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

Discussion: An AU (also known as "principal investigator") is a person whose training and experience have been reviewed and approved by VDH, who is named on the license, and who uses or directly supervises the use of licensed material. The AU's primary responsibility is to ensure that radioactive materials used in his or her particular lab or area are used safely and according to regulatory requirements. The AU is also responsible to ensure that procedures and engineering controls are used to keep occupational doses and doses to members of the public ALARA.

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

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

Training should include the following subjects:

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

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

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

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

Response from Applicant:

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

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

Rule: 12VAC5-481-450 A, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-2260, 12VAC5-481-2270, 12VAC5-481-2280, 12VAC5-481-2310

Criteria: Individuals whose assigned duties involve exposure to radiation and/or radioactive material (from both licensed and unlicensed sources), and in the course of their employment are likely to receive in a year an occupational dose of radiation greater than 1 mSv (100 mrem), must receive instruction commensurate with their duties and responsibilities, as required by 12VAC5-481-2270.

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

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

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

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

Response from Applicant:

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

Item 8: Radioactive Material

Rule: 12VAC5-481-390, 12VAC5-481-430, 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-3730

Criteria: An application for a license will be approved if the requirements of 12VAC5-481-440 are met. In addition, licensees will be authorized to possess and use only those sealed sources and devices that are specifically approved or registered by the NRC or another Agreement State.

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

Table 2: Types of Radioactive Material

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

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

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

If you plan to possess radioactive materials in excess of the quantities listed in **12VAC5-481-3740**, then you must provide with the application either:

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

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

Before proceeding further, applicants should determine if their proposed uses of licensed material are in excess of the quantities specified in **12VAC5-481-3730**. It is not necessary to submit an application to VDH for quantities of radioactive material that are covered by the exemption in **12VAC5-481-390** provided that they are received from entities that are licensed to distribute them. Similarly, certain prepackaged units (typically called kits) containing radioactive material for conducting "*in vitro*" clinical or laboratory tests, are distributed to persons who are generally licensed. Rules related to possession and use of such prepackaged kits under a general license are stated in **12VAC5-481-430 G**. Persons eligible for this general license are limited to physicians, veterinarians in the practice of veterinary medicine, clinical laboratories, and hospitals; however, these persons are required to register with VDH before acquiring or using these units, unless they have a VDH license under **12VAC5-481 'Virginia Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts'**.

Certain devices containing sealed sources of radioactive material, such as Electron Capture Devices in Gas Chromatographs (GCs), are authorized by VDH, the NRC or another Agreement State for distribution to persons who are generally licensed as well as to persons who are specifically licensed. Generally licensed devices can be acquired by the users without obtaining a specific license from VDH. Regulatory requirements for such devices possessed under a general license are stated in **12VAC5-481-430 B**.

Distributors of such devices must provide users with appropriate information related to the acquisition, use, and transfer of these generally licensed devices. Alternatively, GCs may be authorized on an ARDL specific license. **Appendix D** information shall be submitted in support of such a request.

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

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 may be specified. Except as specifically approved by VDH, licensees are required to use irradiators 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.

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

Response from Applicant

Item 8 Radioactive Material (Attach additional pages if necessary)				
UNSEALED SOURCES				
Radioisotope				
Chemical/Physical Form				
Maximum Possession Limit				
Proposed Use				
SEALED SOURCES				
Radioisotope				
Sealed Source Manufacturer or Distributor and Model Number				
Device Manufacturer or Distributor and Model Number				
Maximum Possession Limit				
Proposed Use				

Purpose(s) for Which Licensed Material Will Be Used

Rule: 12VAC5-481-10, 12VAC5-440, 12VAC5-450, 12VAC5-500

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

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

Research and development, as defined in 12VAC5-481-10, does not include research involving the use of licensed material in or on humans. Applicants intending to use licensed materials for medical research involving humans must be authorized to do so pursuant to a license issued under 12VAC5-481 'Virginia Radiation Protection Regulations', Part VII 'Use of Radionuclides in the Healing Arts', and should refer to VAREG, 'Guidance for Medical Use of Radioactive Materials'.

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

Table 3: Sample Format for Providing Information About Requested Radioisotopes

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

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

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

Financial Assurance and Record Keeping for Decommissioning

Rule: 12VAC5-481-100, 12VAC5-481-450 C, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 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 submit a decommissioning funding plan (DFP) or provide a certification of financial assurance (F/A) for decommissioning. All licensees are required to maintain records of information important to the decommissioning of the facility in an identified location until the site is released for unrestricted use. Licensees must transfer these records either to the new licensee before licensed activities are transferred or assigned in accordance with 12VAC5-481-500 B or to VDH before the license is terminated.

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

VDH requirements for F/A and/or a DFP are designed to provide reasonable assurance that the technical and environmental components of decommissioning are carried out and unrestricted use of the facilities is possible at the conclusion and/or termination of licensed activities. The agency wants to ensure that decommissioning will be carried out with minimum impact on public and occupational health and safety and on the environment. These requirements, if applicable, specify that a licensee either set aside funds for decommissioning activities or provide a guarantee through a third party that funds will be available. Applicants are required to submit an F/A and/or a DFP when the possession of radioactive material of half-life (T1/2) greater than 120 days exceeds certain limits. Criteria for determining whether an applicant is required to submit a DFP and/or an F/A (or neither) are stated in 12VAC5-481-450 C.

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

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

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

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

* 1 millicurie = 37 MBq

Note: NRC Regulatory Guide (RG) 3.66, 'Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72', contains approved wording for each mechanism authorized by the rule to guarantee or secure funds except for the Statement of Intent for government licensees.

Record Keeping

The requirements for maintaining records important to decommissioning, including the type of information required, are stated in **12VAC5-481-450 C**. All licensees are required to maintain these records in an identified location until the site is released for unrestricted use. In the event that the licensed activities are transferred to another person or entity, these records shall be transferred to the new licensee prior to transfer of the licensed activities. The new licensee is responsible for maintaining these records until the license is terminated. When the license is terminated, these records shall be transferred to VDH.

12VAC5-481-450 C Requirements for Disposition of Records Important to Decommissioning:

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

OR

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

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

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

Item 9: Facilities and Equipment

Rule: 12VAC5-481-450, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-840, 12VAC5-481-850, 12VAC5-481-860, 12VAC5-481-880

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

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

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

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

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

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

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

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

Response from Applicant:

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

Item 10: Radiation Safety Program

Item 10.1: Radiation Safety Audit Program

Rule: 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-630, 12VAC5-481-990

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

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

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

Currently, the agency's emphasis in inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of radioactive material users to determine if, for example, Operating and Emergency Procedures are available and are being followed.

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

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

Response from Applicant:

Item 10.1 Radiation Safety Audit Program

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

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

Item 10.2: Radiation Monitoring Instruments

Rule: 12VAC5-481-450 A, 12VAC5-481-490 B, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-720, 12VAC5-481-750, 12VAC5-481-1000

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

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

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

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

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

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

VDH requires that calibrations be performed by the instrument manufacturer or a person specifically authorized by VDH, the NRC or another Agreement State, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey instrument calibrations shall submit procedures for review. **Appendix M** provides information about instrument specifications and calibration procedures.

Response from Applicant:

Item 10.2 Radiation Monitoring Instruments (Check one box)

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

OR

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

OR

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

Item 10.3: Material Receipt and Accountability

Rule: 12VAC5-481-90, 12VAC5-481-100, 12VAC5-481-390, 12VAC5-481-400, 12VAC5-481-420, 12VAC5-481-430, 12VAC5-481-450, 12VAC5-481-480 B, 12VAC5-481-490 B, 12VAC5-481-500, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-740, 12VAC5-481-840, 12VAC5-481-900, 12VAC5-481-980, 12VAC5-481-1010, 12VAC5-481-1090, 12VAC5-481-1150, 12VAC5-481-3091, 12VAC5-481-3100, 12VAC5-481 3730

Criteria: Licensees must do the following:

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

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

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

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

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

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

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

12VAC5-481-900 states the requirements for monitoring packages containing licensed material. These requirements are described in **Table 5** below.

Table 5: Package Monitoring Requirements

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

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

12VAC5-481-900 requires that the licensee immediately notify the final delivery carrier and, by telephone and either telegram or facsimile, VDH, when removable radioactive surface contamination or external radiation levels exceeds the limits of **49 CFR 173.443**.

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

'Cradle to Grave' accountability refers to maintaining the radioactive material from the moment it becomes a part of your organization 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 frequently possess radioactive material, which is generally licensed or distributed to them as an exempt quantity in addition to that which is specifically listed on their license.

12VAC5-481-420 and **12VAC5-481-430** provides information regarding generally licensed devices. Any person who acquires, receives, possesses, uses, or transfers a generally licensed

device must do so in accordance with the provisions of the general license. Generally licensed material possessed by a specific licensee may continue to be possessed under a general license. A specific license does not automatically remove general licensee status nor automatically 'move' generally licensed material to the specific license. The agency recognizes that multiple authorizations can create some confusion and, therefore, a specific licensee always has the option of receiving and possessing radioactive materials that "qualify" for a general license, by adding these to its specific license.

Similarly, radioactive material received by a specific licensee, that is distributed to them under an exemption from the requirements for a license, is not subject to the terms and conditions of the specific license. Any person may receive radioactive material that is exempt from the requirements of a license pursuant to **12VAC5-481-90**, **12VAC5-481-390** and **12VAC5-481-400**. Such materials may include 'exempt quantities' of radioactive materials that do not exceed the applicable quantity listed in **12VAC5-481 3730**, as well as items such as smoke detectors and self-luminous watches, that are distributed in accordance with other VDH requirements. Most licensees do not possess or control these types of devices under the provisions of their specific license and the agency does not require or encourage this practice; however, as stated above, the specific licensee always has the option of adding these materials to its license, and controlling them under the conditions of the specific license. In any case, licensees are required to ensure that dose limits are not exceeded, whether or not the dose results from licensed sources or unlicensed sources.

Some facilities may have separate laboratories or locations which use material for in-vitro assay that may be possessed under the general license in **12VAC5-481-430 G**. Each location is a separate general license from the other. The multiple locations are not considered to operate under a single general license and are not considered part of the specific license. The possession limit of 7.4 MBq (200 microcuries), only applies to a total amount of iodine-125 (I-125), iodine-131 (I-131), selenium-75 (Se-75), iron-59 (Fe-59) or cobalt-57 (Co-57) used or stored in one location.

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

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

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

To ensure that only trained, experienced, and authorized individuals use or supervise the use of licensed material, the RSO should know who has requested an order of licensed material and the types and amounts of licensed materials requested. Control procedures should also be established for the procurement of licensed materials that may be obtained outside the normal

channels, e.g., through the loan or other transfer of materials without purchase or through surplus. A sample procedure for ordering and receiving radioactive material is included in **Appendix N**.

VDH requirements applicable to transfers are stated in **12VAC5-481-570**. Sample policy transfer statements are included in **Appendix N**. Transfer of licensed materials within the facility may require special procedures to ensure proper control. In many facilities, pieces of laboratory equipment or components including refrigerators and freezers will become contaminated. Removal of these items for maintenance, repair, or disposal should also be carefully controlled.

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

Table 6: Record Maintenance

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

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

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

See **Item 12** "Waste Management" for additional information.

Information about locations where licensed material is used or stored are among the records important to decommissioning and required by **12VAC5-481-450 C**. See the section on "Financial Assurance and Record Keeping for Decommissioning" for additional information.

Response from Applicant:

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

Unsealed Sources

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

Sealed Sources

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

OR

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

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

Item 10.4: Occupational Dosimetry

Rule: 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-650, 12VAC5-481-670, 12VAC5-481-700, 12VAC5-481-710, 12VAC5-481-750, 12VAC5-481-760, 12VAC5-481-770, 12VAC5-481-1040, 12VAC5-481-1130, 12VAC5-481-1140, 12VAC5-481-2280

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

- Adults who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
 - 5 mSv (0.5 rem) deep-dose equivalent.
 - 15 mSv (1.5 rems) eye dose equivalent.
 - 50 mSv (5 rems) shallow-dose equivalent to the skin.
 - 50 mSv (5 rems) shallow-dose equivalent to any extremity.
- Minors who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
 - 0.5 mSv (0.05 rem) deep-dose equivalent.
 - 1.5 mSv (0.15 rem) eye dose equivalent.
 - 5 mSv (0.5 rem) shallow-dose equivalent to the skin.
 - 5 mSv (0.5 rem) shallow-dose equivalent to any extremity.
- Declared pregnant women who are likely to receive an annual dose from occupational exposures in excess of 1 mSv (100 mrem) deep-dose equivalent, although the dose limit applies to the entire gestation period; and
- Individuals entering a high or very high radiation area.

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

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

Discussion: According to **12VAC5-481-760**, if an adult (individual) is likely to receive in 1 year a dose greater than 10% of any applicable limit, monitoring for occupational exposure is required. The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose. This evaluation need not be made for every individual; evaluations can be made for employees with similar job functions or work areas. Further guidance on evaluating the need to provide monitoring is provided in NRC Regulatory Guide 8.34, *'Monitoring Criteria and Methods to Calculate Occupational Doses'*, dated July 1992.

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

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

If the prospective dose evaluation shows that the individual is likely to exceed 10% of an applicable limit (**Table 7**), monitoring is required per **12VAC5-481-760**. Recordkeeping of the results of monitoring performed regardless of the actual dose received is required by **12VAC5-481-1040**.

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

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

Table 7: Occupational Dose Limits For Adults
Occupational Dose Limits for Adults (12VAC5-481-640)

<u>Body Location</u>	<u>Dose (Annual)</u>
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	

Response from Applicant:

<p>Item 10.4 Occupational Dosimetry (Check one box)</p> <p><input type="checkbox"/> We will maintain, for inspection by VDH, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in 12VAC5-481-640.</p> <p align="center">OR</p> <p><input type="checkbox"/> We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged at a frequency recommended by the processor. (12VAC5-481-750)</p>

Item 10.5: Public Dose

Rule: 12VAC5-481-10, 12VAC5-481-630, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-840, 12VAC5-481-1050, 12VAC5-481-1110, 12VAC5-481-1870

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

Discussion: Public dose is defined in **12VAC5-481-10** as *"the dose received by a member of the public from exposure to sources of radiation released by the licensee or registrant, or to any other source of radiation under the control of the licensee or registrant. Public dose does not include occupational dose, or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 12VAC5-481-1870, or from voluntary participation in medical research programs."*

Whether the dose to an individual is an occupational dose or a public dose depends on the individuals assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) the individual is in when the dose is received. For guidance about accepted methodologies for determining dose to members of public, please refer to **Appendix O**.

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

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

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

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

The licensee should review these major pathways and decide which are applicable to its operations.

Licensees should design a monitoring program to ensure compliance with **12VAC5-481-720**. The extent and frequency of monitoring will depend upon each licensee's needs. For additional guidance regarding monitoring of effluents, refer to the section titled "Surveys".

12VAC5-481-1050 requires that licensees maintain records sufficient to demonstrate compliance with the dose limits for members of the public until VDH terminates the license. Refer to **Appendix O** for additional guidance regarding compliance with the recordkeeping requirements.

Response from Applicant:

Item 10.5 Public Dose

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

Item 10.6: Safe Use of Radionuclides and Emergency Procedures

Rule: 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-860, 12VAC5-481-870, 12VAC5-481-880, 12VAC5-481-890, 12VAC5-481-900, 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1150, 12VAC5-481-2260, 12VAC5-481-3091, 12VAC5-481-3740

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

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

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

General Safety Procedures

The written procedures should include the following elements:

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

These procedures should include policies for:

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

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

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

Security Procedures

All licensed materials that are stored in controlled or unrestricted areas must be secured from unauthorized access or removal, so that individuals who are not knowledgeable about radioactive materials can not be exposed to or contaminated by the material, and can not take the material. When any licensed materials are in use in controlled or unrestricted areas, they must be under constant surveillance so that the radiation worker can prevent others from becoming contaminated by or exposed to the material, or to prevent persons from removing the material from the area. Acceptable methods for securing material will vary from one facility to another. Some alternatives used by licensees include: storage and use of licensed materials only in restricted areas; limiting access to an entire facility or building or portion of the building only to radiation workers; providing storage areas that can be locked to prevent access to the material; and implementing procedures that require a radiation worker to be within "line of sight" of the materials whenever licensed materials are in use. Applicants should develop procedures that clearly state acceptable methods to secure licensed material at their facility. Particular attention may be required to security procedures at facilities which may have unusual needs due to the activities performed, such as hot cells, animal care facilities, and waste processing facilities.

Emergency Procedures

Accidents and emergencies can happen during any operation with radioisotopes, including their transportation, use, transfer, and disposal. Such incidents can result in contamination or release of material to the environment, and unintended radiation exposure to workers and members of the public. In addition, loss or theft of licensed material, sabotage, fires, floods, etc., can adversely affect the safety of personnel and members of the public. It is therefore necessary to develop written procedures to minimize, as much as possible, the impact of these incidents on personnel, members of the public, and the environment. Applicants who plan to possess quantities of material in excess of the applicable amounts listed in **12VAC5-481-3740** are also required to submit an "Emergency Response Plan for Responding to a Release".

Applicants should establish written procedures to handle events ranging from a minor spill to a major accident that may require intervention by outside emergency response personnel. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of users and the radiation safety staff.

Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, the licensee staff should have a clear understanding of their role in an emergency with step-by-step instructions and clear direction of whom to contact.

Licensees should have readily available a sufficient number of appropriate and calibrated survey instruments. Emergency spill kits should be strategically placed in well-marked locations for use by all users and the radiation safety staff. All equipment should be periodically inspected for proper operation and replenished as necessary. **Appendix P** includes model emergency procedures. Applicants shall develop procedures incorporating the safety features included in these model procedures.

Collection of Bioassay Samples

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

- Type of bioassay that must be performed (direct or indirect);
- Number of samples or data points to be collected;

- Frequency of sampling (hourly, daily, weekly, once, etc.);
- Size of the sample to be collected (24-hour urine collection);
- Ease/difficulty of sample collection; and
- Need for written instructions to be provided to the sample collector, who may be the contaminated individual.

Response from Applicant:

<p>Item 10.6 Safe Use Of Radionuclides And Emergency Procedures (Check all that apply)</p> <p><input type="checkbox"/> We will develop, implement and maintain safe use of radionuclides and emergency procedures that will meet the criteria in the section titled "Safe Use of Radionuclides and Emergency Procedures" in VAREG 'Guidance for Academic, Research and Development and Other Licenses of Limited Scope'. (Procedures are Attached)</p>

Item 10.7: Surveys

Rule: 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-740, 12VAC5-481-750, 12VAC5-481-1000, 12VAC5-481-1010, 12VAC5-481-1110, 12VAC5-481-1150

Criteria: Licensees are required by 12VAC5-481-750 to make surveys of potential radiological hazards in their workplace. VDH requires testing to determine whether there is any radioactive leakage from sealed sources. Records of surveys and leak tests results must be maintained.

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

Radiation surveys are used to detect and evaluate contamination of:

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

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

12VAC5-481-750 states that surveys are required when it is reasonable under the circumstances to evaluate a radiological hazard and when necessary for the licensee to comply with the requirements. Many different types of surveys may need to be performed due to the particular use of licensed materials. The most important are as follows:

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment;
- Measurements of radioactive material concentrations in air for areas where radioactive materials are handled or processed in unsealed form and where

operations could expose workers to the inhalation of radioactive material or where licensed material is or could be released to unrestricted areas;

- Measurements of radioactive material concentrations in water that is released to the environment or to the sanitary sewer;
- Bioassays to determine the kinds, quantities or concentration, and in some cases, the location of radioactive material in the human body. A bioassay can be made by direct measurement (in vivo counting) or by analysis and evaluation of material excreted or removed from the human body; and
- Surveys of external radiation exposure levels in both restricted and unrestricted areas.

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

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

12VAC5-481 'Virginia Radiation Protection Regulations' does not specify limits for surface contamination. Each applicant should propose and justify what removable surface contamination limits will be allowable before decontamination will be performed in each work area. **Table 13** and **14** in **Appendix Q** contain contamination limits that are acceptable to VDH.

Sealed Source and Plated Foil Leak Test

12VAC5-481-740 requires the performance of leak tests of sealed and plated foil sources (e.g., GC) at interval not to exceed six months unless otherwise approved by the NRC or another Agreement State and specified by the SSD Registration Certificate. The measurement of the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 Ci) of the radioisotope contained in the source or foil.

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

Leak tests are not required if:

- Sources contain only hydrogen-3 (H-3);
- Sources contain only radioactive material with a half-life of less than 30 days;
- Sources contain only a radioactive gas;
- Sources contain 3.7 MBq (100 μ Ci) or less of beta-emitting or gamma-emitting material or 370 kBq (10 μ Ci) or less of alpha-emitting material; or

- Sources are stored and are not being used (must be leak tested every 5 years and before use or transfer).

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

Response from Applicant:

Item 10.7 Surveys (Check all that apply)

We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q of VAREG 'Guidance for Academic, Research and Development and Other Licenses of Limited Scope'.

IF SEALED SOURCES ARE USED

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

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

Organization Name _____ License Number _____

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

OR

We will perform our own leak testing and sample analysis. We will follow the model procedures in Appendix R of VAREG 'Guidance for Academic, Research and Development and Other Licenses of Limited Scope'.

OR

We will submit alternative procedures. (Procedures are attached)

Item 10.8: Transportation

Rule: 12VAC5-481-100, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-2980, 12VAC5-481-3000, 12VAC5-481-3010, 12VAC5-481-3020, 12VAC5-481-3070, 12VAC5-481-3080, 12VAC5-481-3091, 12VAC5-481-3100, 12VAC5-481-3110, 12VAC5-481-3130, 12VAC5-481-3710, 49 CFR Parts 171-178

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

Discussion: Packages shipped by ARDL licensees frequently meet the "Limited Quantity" criteria as described in 49 CFR 173.421, and therefore could be exempt from certain DOT requirements, but they may be subject to other, less restrictive DOT requirements (e.g., 49 CFR 173.422 and 173.424; also see **Appendix S** for more information).

If they are not exempted, however, licensed material, including radioactive waste, must be packaged and transported in accordance with VDH and the DOT requirements if the transportation involves common carriers or the use of public highways. Licensees should

develop and maintain their own radiation safety procedures for transporting licensed material within their own facilities if it does not involve the use of public highways.

Licenseses should consider the safety of all individuals who may handle or may come into contact with the packages containing licensed material. Therefore, the primary considerations in packaging licensed material should be to ensure that the package integrity is not compromised during transport and that the radiation levels (including removable contamination levels) at the package surfaces not only meet the regulatory requirements of **12VAC5-481-3070** but are ALARA.

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

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

Response from Applicant:

Item 10.8 Transportation

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

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

Item 10.9: Minimization of Contamination

Rule: 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-630, 12VAC5-481-740, 12VAC5-481-1150, 12VAC5-481-1161

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

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

- Implementation of and adherence to good health physics practices in operations;
- Minimization of areas, to the extent practicable, where licensed materials are used and stored;
- Maximization of the frequency of surveys, within reason, to minimize spread of contamination in the event of a spill;
- Choice of isotope to be used, whenever practical, in consideration of half-life and chemical composition;
- Appropriate filtration of effluent streams;
- Use of non-porous materials for laboratory bench tops, flooring, etc.;

- Ventilation stacks and ductwork with minimal lengths and minimal abrupt changes in direction;
- Use of appropriate plumbing materials with minimal pipe lengths and traps; and
- Minimization of the number of disposal sites (sinks) where liquid waste is disposed.

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

Response from Applicant:

Item 10.9 Minimization of Contamination

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

Item 10.10: Termination of Activities

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-1161

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

- Notify the agency, in writing, within 60 days of:
 - The expiration of its license;
 - A decision to permanently cease licensed activity at the entire site or in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to VDH requirements;
 - No principal activities have been conducted at the entire site under the license for a period of 24 months;
 - No principal activities have been conducted for a period of 24 months in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to VDH requirements.
- Submit a decommissioning plan, if required by **12VAC5-481-510**;
- Conduct decommissioning, as required by **12VAC5-481-510** and **12VAC5-481-1161**; and
- Submit to the agency, a completed VDH Form, 'Certificate of Disposition of Materials' (**Appendix B**) and demonstrate that the premises are suitable for release for unrestricted use (e.g. results of final survey).
- Before a license is terminated, send the records important to decommissioning to VDH. If licensed activities are transferred or assigned in accordance with **12VAC5-481-500 B**, transfer records important to decommissioning to the new licensee.

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

- NRC NUREG-1727, 'NMSS Decommissioning Standard Review Plan' dated September 2000.
- NRC NUREG/BR-0241, 'NMSS Handbook for Decommissioning Fuel Cycle and Materials Licenses', dated March 1997, contain the current regulatory guidance concerning decommissioning of facilities and termination of licenses.
- Appendix B of NRC NUREG/BR-0241 contains a comprehensive list of NRC's decommissioning regulations and guidance.
- NRC NUREG-1727 contains a list of superceded guidance; however, due to ongoing revisions, applicants are encouraged to consult with VDH staff regarding updates of decommissioning guidance.
- NRC NUREG-1575, 'Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)', dated December 1997, should be reviewed by licensees who have large facilities to decommission.
- NRC NUREG-1727 includes a table (Table C2.2) of acceptable license termination screening values of common beta/gamma radionuclides for building surface contamination.
- NRC NUREG-1727 also contains methods for conducting site-specific dose assessments for facilities with contamination levels above those in the table.

Response from Applicant:

Item 10.10 Termination Of Activities

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

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

Item 11: Waste Management

Rule: 12VAC5-481-100, 12VAC5-481-430 G, 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-720, 12VAC5-481-750, 12VAC5-481-910, 12VAC5-481-920, 12VAC5-481-930, 12VAC5-481-940, 12VAC5-481-950, 12VAC5-481-960, 12VAC5-481-970, 12VAC5-481-971, 12VAC5-481-980, 12VAC5-481-1060, 12VAC5-481-1870, 12VAC5-481-1890, 12VAC5-481-2980, 12VAC5-481-3100, 12VAC5-481-3690, 12VAC5-481-3710

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

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

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

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

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

Applicants should describe their program for management and disposal of radioactive waste. The program should include procedures for handling of waste, safe and secure storage, characterization, minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. **12VAC5-481 'Virginia Radiation Protection Regulations'** requires that licensees maintain all appropriate records of disposal of radioactive waste. The U.S. Environmental Protection Agency (EPA) issued guidance for developing a comprehensive program to reduce hazardous waste that, in many instances, may also include radioactive waste. NRC transmitted these guidelines to licensees in NRC IN-94-23, '*Guidance to Hazardous, Radioactive, and Mixed Waste Minimization Program*' dated March 1994.

Disposal By Decay-in-storage (DIS)

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

Applicants should assure that adequate space and facilities are available for the storage of such waste. Licensees can minimize the need for storage space, if the waste is segregated according to physical half-life. Waste containing radioisotopes of physical half-lives within a certain range may be stored in one container and allowed to decay for at least ten half-lives of the longest-

lived radioisotope in the container. Procedures for management of such waste should include methods of segregation, surveys prior to disposal, and maintenance of records of disposal. Records should include the date when the waste was put in storage for decay, date when ten half-lives of the longest-lived radioisotope have transpired, date of disposal, and results of final survey before disposal as ordinary trash. Additionally, a procedure for disposal of radioactive waste by DIS, which incorporates the above guidelines, is provided in **Appendix T**.

Release Into Sanitary Sewerage

12VAC5-481-930 authorizes disposal of radioactive waste by release into a public sanitary sewerage system if each of the following conditions is met:

- Material is readily soluble (or is easily dispersible biological material) in water;
- Quantity of licensed material that the licensee releases into the sewer each month averaged over the monthly volume of water released into the sewer does not exceed the concentration specified in **12VAC5-481-3690**,
- If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit in **12VAC5-481-3690** cannot exceed unity; and
- Total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 185 GBq (5 Ci) of H-3, 37 GBq (1 Ci) of C-14, and 37 GBq (1 Ci) of all other radioisotopes combined.

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

12VAC5-481-930 is not applicable for releases to a private sewerage treatment system, a septic system, or leach fields. Licensees may make releases to these systems as effluents released to unrestricted areas pursuant to **12VAC5-481-720**. However, if licensed material is released to a private sewage treatment system, septic system, or leach field, the sludge or other solids from these systems may become contaminated with radioactive material. Such sludges may be required to be disposed of as radioactive waste, using one of the methods described as described in this section of this VAREG.

Applicants should provide procedures that will ensure that all releases of radioactive waste into the sanitary sewerage meet the criteria stated in **12VAC5-481-930** and do not exceed the monthly and annual limits specified in **12VAC5-481-3690**. Licensees are required to maintain accurate records of all releases of licensed material into the sanitary sewerage. A program for disposal of radioactive waste via sanitary sewer is described in **Appendix T**.

Transfer to an Authorized Recipient

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

The shipper must provide all information required in NRC's Uniform Low-Level Radioactive Waste Manifest, and transfer this recorded manifest information to the intended recipient in accordance with **12VAC5-481-3710**. Each shipment manifest must include a certification by the waste generator, as specified in Section II of the **12VAC5-481-3710**. Each person involved in the transfer for disposal and disposal of waste, including waste generator, waste collector, waste processor, and disposal facility operator, must comply with requirements specified in Section III of the above **12VAC5-481-3710**.

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

Disposal of Specific Waste As If It Were Not Radioactive

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

- Liquid scintillation media (including vials and other items contaminated with liquid scintillation media) containing no more than 1.85 kBq (0.05 μ Ci) of H-3 or C-14 per gram of the medium; and
- Animal carcasses or animal tissue containing no more than 1.85 kBq (0.05 μ Ci) of H-3 or C-14 per gram averaged over the weight of the entire animal.

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

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

Alternate Methods

Applicants may also request alternate methods for the disposal of radioactive waste generated at their facilities. Such requests must describe the waste containing licensed material, including the physical and chemical properties that may be important to assess risks associated with the waste,

and the proposed manner and conditions of waste disposal. Additionally, the applicant must submit its analysis and evaluation of pertinent information on the nature of the environment, nature and location of other affected facilities and procedures to ensure that radiation doses are maintained ALARA and within regulatory limits.

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

Response from Applicant:

<p>Item 11 Waste Management (Check all that apply)</p> <p><input type="checkbox"/> We will follow the model waste procedures published in Appendix T of VAREG 'Guidance for Academic Research and Development and Other Licenses of Limited Scope'.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will follow: <input type="checkbox"/> Decay-In-Storage or <input type="checkbox"/> Disposal of Liquids Into Sanitary Sewerage waste procedures that are published in Appendix T of VAREG 'Guidance for Academic Research and Development and Other Licenses of Limited Scope'.</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> We will develop, implement and maintain procedures for waste collection, storage and disposal by any of the authorized methods described in Item 11 "Waste Management" of VAREG 'Guidance for Academic Research and Development and Other Licenses of Limited Scope'. We will contact the agency for guidance to obtain approval of any method(s) of waste disposal other than those discussed in Item 11 "Waste Management" of VAREG 'Guidance for Academic Research and Development and Other Licenses of Limited Scope'. (Procedures are attached)</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> If access to a radioactive waste burial site is unavailable, we will request authorization for extended interim storage of waste. We will refer to NRC IN 90-09 'Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licenses', dated February 1990, for guidance and submit the required information with this applications.</p> <p style="text-align: center;">IF SEALED SOURCES ARE USED</p> <p><input type="checkbox"/> We will return sealed sources/devices to the manufacturer, distributor or an organization licensed by VDH, the NRC or another Agreement State.</p> <p>NOTE: Applicants do not need to provide information to VDH if they plan to dispose of LLW via transfer to another authorized recipient or to dispose of liquid scintillation media or animals containing low levels of H-3 or C-14 as authorized by 12VAC5-481-910</p>
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Item 12: License Fees

Rule: 12VAC5-481-491

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

Response from Applicant:

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

Item 13: Certification

Criteria:

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

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

Response from Applicant:

Item 13	
I hereby certify that this application was prepared in conformance with 12VAC5-481 'Virginia Radiation Protection Regulations' and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.	
SIGNATURE - Applicant Or Authorized Individual	Date signed:
Print Name and Title of above signatory.	

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

Appendix A

VDH Form

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



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

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

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

APPLICATION TYPE

Item 1 Type Of Application (Check one box)

New License Renewal License Number

CONTACT INFORMATION

Item 2 Name And Mailing Address Of Applicant:

Item 3 Person To Contact Regarding Application:

Applicant’s Telephone Number (Include area code):

() - x

Contact’s Telephone Number (Include area code):

() - x

LOCATION OF RADIOACTIVE MATERIAL

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

Address

Telephone Number (Include area code)

() - x

Address

Telephone Number (Include area code)

() - x

Address

Telephone Number (Include area code)

() - x

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

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

RADIATION SAFETY OFFICER

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

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

Name:

Telephone (Include Area Code) () -

X

AND

- Before obtaining radioactive materials, the proposed RSO will have successfully completed one of the training courses described in the section titled "Individual(s) Responsible for Radiation Safety Program and Their Training and Experience" in VAREG 'Guidance for Academic, Research and Development, and other Licenses of Limited Scope'.

AND

Before being named as the RSO, future RSOs will have successfully completed one of the training courses, described in the section titled "Individual(s) Responsible for the Radiation Safety Program and Their Training and Experience" in VAREG 'Guidance for Academic, Research and Development, and other Licenses of Limited Scope'.

OR

- Alternative information demonstrating that the proposed RSO is qualified by training or experience.

AUTHORIZED USERS AND TRAINING

Item 6 Authorized Users (Check both boxes)

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

AND

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

Item 7 Training For Individuals Working In Or Frequenting Restricted Areas

(Occupationally exposed individuals and ancillary personnel) (Check box)

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

RADIOACTIVE MATERIAL

Item 8 Radioactive Material (Attach additional pages if necessary)

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

SEALED SOURCES				
Radioisotope				
Sealed Source Manufacturer or Distributor and Model Number				
Device Manufacturer or Distributor and Model Number				
Maximum Possession Limit				
Proposed Use				

FACILITIES AND EQUIPMENT

Item 9. Facilities and Equipment (Check all that apply and attach the requested information.)

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

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

AND, IF APPLICABLE

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

AND/OR

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

RADIATION SAFETY PROGRAM

Item 10.1 Radiation Safety Audit Program

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

Item 10.2 Radiation Monitoring Instruments (Check one box)

- We will use instruments that meet the radiation monitoring instruments specifications published in Appendix M of VAREG 'Guidance for Academic, Research and Development and Other Licenses of Limited Scope'. We reserve the right to upgrade our survey instruments as necessary. The instruments will be calibrated by an organization licensed by VDH, the NRC or another Agreement State to perform calibrations.

OR

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

OR

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

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

Unsealed Sources

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

Sealed Sources

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

OR

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

Item 10.4 Occupational Dosimetry (Check one box)

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

OR

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

Item 10.5 Public Dose

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

Item 10.6 Safe Use of Radionuclides and Emergency Procedures (Check box)

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

Item 10.7 Surveys (Check all that apply)

- We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q of VAREG 'Guidance for Academic, Research and Development and Other Licenses of Limited Scope'.

IF SEALED SOURCES ARE USED

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

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

Organization Name _____

License Number _____

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

OR

- We will perform our own leak testing and sample analysis. We will follow the procedures published in Appendix R of VAREG 'Guidance for Academic, Research and Development and Other Licenses of Limited Scope'.

OR

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

Item 10.8 Transportation

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

Item 10.9 Minimization of Contamination

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

Item 10.10 Termination Of Activities

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

Item 11 Waste Management (Check all that apply)

We will follow the model waste procedures published in Appendix T of VAREG 'Guidance for Academic Research and Development and Other Licenses of Limited Scope'.

OR

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

OR

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

OR

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

IF SEALED SOURCES ARE USED

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

NOTE: Applicants do not need to provide information to VDH if they plan to dispose of LLW via transfer to another authorized recipient or to dispose of liquid scintillation media or animals containing low levels of H-3 or C-14 as authorized by 12VAC5-481-910.

SPECIFIC LICENSE FEE

Item 12 License Fees (Refer to 12VAC5-490.)

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

Item 13

I hereby certify that this application was prepared in conformance with 12VAC5-481 'Virginia Radiation Protection Regulations' and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.

SIGNATURE - Applicant Or Authorized Individual	Date signed
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Print Name and Title of above signatory

Appendix B

VDH Form

‘Certificate of Disposition of Material’



CERTIFICATE OF DISPOSITION OF MATERIALS

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

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

CONTACT INFORMATION

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

TERMINATION AND DISPOSITION INFORMATION

The following information is provided in accordance with **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 Correspondence Delegation Letter

SAMPLE CORRESPONDENCE DELEGATION LETTER

[*date*]

[*name and address*]

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

To Radioactive Materials Program Director:

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

Print Name

Appendix D

Gas Chromatography Devices

Gas Chromatography Devices

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

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

Rule

Licensees are subject to all applicable provisions of the regulations in **12VAC5-481 'Virginia Radiation Protection Regulations'** as they pertain to GC's.

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

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

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

Specify the street address, city, and state or other descriptive address (e.g., on Highway 58, 5 miles east of the intersection of Highway 58 and State Route 19, Anytown, VA, Zip) for each facility at which licensed material will be used or stored. **A Post Office Box address is not acceptable.** In addition, state whether the GC will be used at temporary jobsites.

Item 5: Radiation Safety Officer

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

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

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

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

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

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

Item 8: Radioactive Material

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

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

Purpose For Which Licensed Material Will Be Used

Specify the intended purpose for each GC to be used.

Item 9: Facilities and Equipment

12VAC5-481-450 A states that an application will be approved if the applicant's proposed equipment and facilities are adequate to protect health and to minimize danger to life or property. **12VAC5-481-840 A** also states that licensed material stored in an unrestricted area must be secured from unauthorized removal, and licensed materials in an unrestricted area and not in storage must be under the constant surveillance and immediate control of the licensee.

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

Item 10: Radiation Safety Program

Item 10.1 Audit Program

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

Item 10.2 Radiation Monitoring Instruments

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

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

Item 10.3 Material Receipt and Accountability

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

Item 10.4 Occupational Dose

Personnel monitoring devices are not required for the following:

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

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

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

Item 10.6 Safe Use of Radionuclides and Emergency Procedures

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

Item 10.7 Surveys (Leak Testing)

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

When issued, a license will require performance of leak tests of sealed/plated foil sources at intervals as approved by the NRC or another Agreement State and as specified by the SSD Registration Certificate. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 Ci) of radioactivity.

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

Item 10.8 Transportation

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

Item 10.9 Minimization of contamination

New license applicants are required by **12VAC5-481-450 A** to describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

Item 11: Waste Management

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

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

Appendix E

**Information Needed for
Transfer of Control Application**

Information Needed for Transfer of Control Application

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

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

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

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

1. Provide a complete description of the transaction (transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact who VDH may contact if more information is needed.
2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.
3. Describe any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.
4. Describe the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.
5. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to VDH, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.
6. Confirm that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

Reference: The information above is derived from Information Notice 89-25, Revision 1, "*Unauthorized Transfer of Ownership or Control of Licensed Activities*," which is available at the NRC's webpage at <http://www.nrc.gov>.

Appendix F

Reserved

Appendix G

Guidance on Decommissioning Funding Plan and Financial Assurance

Guidance on Decommissioning Funding Plan and Financial Assurance

Table 8 and 9 are used to determine the need for certification of financial assurance (F/A) for decommissioning or a decommissioning funding plan (DFP), as required by **12VAC5-481-450 C**. **Table 9** lists isotopes with a half-life of greater than or equal to 120 days. It is derived from the table given in **12VAC5-481-3750** and gives adjusted activities to assist in the determination. If the applicant proposes to use isotopes with a half-life greater than or equal to 120 days, divide the requested possession limit (in μCi) of the isotope by the value for that isotope in **Table 9**. If the material requested is in an unsealed form, use the value in the unsealed column. If the material requested is in a sealed form, use the value in the sealed column. Place the fraction in the proper column in worksheet **Table 8**. Add the fractions in the column and place the total in the row labeled total (i.e., "sum of the ratios").

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

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

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

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

Table 9: Isotopes With Half-lives Greater Than or Equal to 120 Days

Isotope	Unsealed (μCi)	Sealed (μCi)
americium-241	10	1×10^8
antimony-125	10000	1×10^{11}
barium-133	10000	1×10^{11}
cadmium-109	10000	1×10^{11}
calcium-45	10000	1×10^{11}
carbon-14	100000	1×10^{12}
Cerium-144	1000	1×10^{10}
Cesium-134	1000	1×10^{10}
Cesium-135	10000	1×10^{11}
Cesium-137	10000	1×10^{11}
Chlorine-36	10000	1×10^{11}
Cobalt-60	1000	1×10^{10}
Europium-152 (13 yr)	1000	1×10^{10}
Europium-154	1000	1×10^{10}
europium-155	10000	1×10^{11}
gadolinium-153	10000	1×10^{11}
gold-198	100000	1×10^{12}
hydrogen-3	1000000	1×10^{13}
indium-115	10000	1×10^{11}
iodine-129	100	1×10^9
iron-55	100000	1×10^{12}
krypton-85	100000	1×10^{12}
manganese-54	10000	1×10^{11}
nickel-59	100000	1×10^{12}
nickel-63	10000	1×10^{11}
niobium-93m	10000	1×10^{11}
platinum-193	100000	1×10^{12}
polonium-210	100	1×10^9
promethium-147	10000	1×10^{11}
rubidium-87	10000	1×10^{11}
ruthenium-106	1000	1×10^{10}
silver-110m	1000	1×10^{10}
strontium-90	100	1×10^9
technetium-97	100000	1×10^{12}
technetium-99	10000	1×10^{11}
thallium-204	10000	1×10^{11}
thulium-170	10000	1×10^{11}
thulium-171	10000	1×10^{11}
tungsten-181	10000	1×10^{11}
Zinc-65	10000	1×10^{11}
Zirconium-93	10000	1×10^{11}
Any alpha emitting Radionuclides not listed above with a half-life greater than or equal to 120 days.	10	1×10^8
Any radionuclide other than alpha emitting radionuclides, not listed above with a half-life greater than or equal to 120 days.	100	1×10^9

Appendix H

Considerations for Laboratory Animal and Veterinary Medical Uses

Considerations for Laboratory Animal and Veterinary Medical Uses

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

I. AS LOW AS IS REASONABLY ACHIEVABLE (ALARA)

12VAC5-481-630 requires that licensees use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

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

For example, a licensee may establish release criteria for cats treated with iodine-131 of 0.5 millirem/hour at one foot from the surface of the body closest to the thyroid. This would involve confining the cats at the veterinary facility until the dose rate falls to that level. This will ensure that persons caring for the cat after discharge will not be exposed to more than 100 millirem [see 12VAC5-481-720] as long as direct contact with the cat is restricted to less than 2 hours a day.

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

II. LICENSEE'S FACILITY DESIGN

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

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

III. LABORATORY ANIMALS

A. Training

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

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

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

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

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

B. Contamination Control and Waste Handling

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

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

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

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

1. Only trained individuals shall be involved in the care and handling of animals that have been administered radioactive materials.

2. The door(s) to animal housing areas shall be locked at all times when animals are present. Only authorized personnel trained in radiation safety shall have access to these areas.
3. The door(s) to animal housing areas, and each cage containing a radioactive animal, shall be conspicuously posted with a "Caution Radioactive Material" sign.
4. Authorized personnel must record the appropriate information and sign the log near the door each time they enter or leave the animal housing area.
5. Personnel providing care to animals shall wear lab coats, disposable gloves (and boots, if appropriate), and whole body dosimeters (extremity dosimeters may also be required).
6. Disposable gloves and boots shall be removed at the entrance and placed in a radioactive waste container before leaving the housing area. Hands, feet, and clothing shall be checked for contamination at this time using a portable survey meter.
7. Animals shall be fed and watered using disposable dishes that will be placed, after use, in the radioactive waste container.
8. Animal excreta shall be collected daily, sealed in plastic bags, properly labeled, and frozen (if necessary). Excreta may not be disposed of as normal waste until the radiation levels from it have reached background.
9. Adequate precautions must be employed for the transfer of treated animals through unrestricted areas to prevent contamination of these areas by excreta.
10. In case of animal death, the carcass must be frozen and stored as radioactive waste until its radiation levels have reached background.
11. A radioactive contamination survey of the housing area shall be performed each day during which an animal is housed.
12. The animal housing area shall not be used for other purposes until surveys indicate that it is free of contamination.

D. Animals Used for Research in the Environment

Before a researcher releases an animal that has been injected with a radiopharmaceutical or has had radioactive seeds implanted, the researcher will ensure that the dose that members of the public will receive from the animal is within limits of **12VAC5-481-720**. **12VAC5-481-720** requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year and that the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour. Further, the researcher may be required to perform an assessment of the impact the radioactive material will have on the environment (See the section titled "Purpose(s) for Which Licensed Material Will Be Used" in **Item 8** "Radioactive Material").

IV. VETERINARY MEDICAL USE

A. Training

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

Training should include the following subjects:

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

- Hands-on Use of Radioactive Materials.

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

B. Responsibilities of Veterinarians

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

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

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

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

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

Such counseling and consideration must be documented.

D. Contamination Control and Waste Handling

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

E. Release of Animals from a Licensee's Facility

Before a veterinarian releases an animal that has been injected with a radiopharmaceutical or has had radioactive seeds implanted, the veterinarian must ensure that the dose that members of the public (including the animal's caretaker) will receive from the animal is within limits of **12VAC5-481-720**. **12VAC5-481-720** requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year and the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour. Furthermore, licensees should provide instructions to the animal's caretaker to keep doses ALARA.

F. Instructions to Animal Caretaker Upon Release

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

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

1. Owner Information and Consent Form

EXAMPLE OWNER INFORMATION AND CONSENT FORM

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

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

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

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

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

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

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

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

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

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

NO SPECIAL SAFETY PRECAUTIONS ARE NEEDED AFTER

Date: _____

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

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

EXAMPLE OWNER INFORMATION AND CONSENT FORM

(cont'd)

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

6. If your cat vomits/soils outside the litter box, use normal cleaning procedures. Seal all soiled paper cleaning materials in a ziploc bag. Place this bag into a second ziploc bag, seal and put in outside trash with soiled litter. Wash hands thoroughly.
7. Anyone pregnant or younger than 18 should not handle the soiled litter.
8. Keep your cat away from food preparation areas.
9. Instruct children to avoid the cat, and wash their hands if they touch it. Small children may not remember or understand these rules, so take extra precautions by having them wash their hands often, especially before eating.
10. If your pet must be seen by a veterinarian prior to the release date listed on this form, please inform the doctor of the type of treatment that your cat received and the date it was treated. Show this form to the doctor prior to the examination.
11. If you pet should die prior to the date listed on this form, please notify

Dr. _____ at _____
(veterinarian) (phone)

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

Owner's Signature _____ Date _____

Veterinarian's Signature _____ Date _____

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

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

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

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

Example Radiopharmaceutical Instructions

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

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

Sample Instructions to Caretakers of Animals Implanted with Sealed Sources

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

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

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

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

Telephone _____ at _____.

Appendix I

Radiation Safety Officer Duties and Responsibilities

Radiation Safety Officer Duties and Responsibilities

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

- Ensure that licensed material possessed by the licensee is limited to the types and quantities of radioactive material listed on the license.
- Maintain documentation that demonstrates that the dose to individual members of the public does not exceed the limit specified in **12VAC5-481-720**.
- Ensure security of radioactive material.
- Posting of documents as required by **12VAC5-481-860**.
- Ensure that licensed material is transported in accordance with applicable VDH and DOT requirements.
- Ensure that radiation exposures are "ALARA."
- Oversee all activities involving radioactive material, including monitoring and surveys of all areas in which radioactive material is used.
- Act as liaison with VDH and other regulatory authorities.
- Provide necessary information on all aspects of radiation protection to personnel at all levels of responsibility, pursuant to **12VAC5-481 'Virginia Radiation Protection Regulations'**.
- Oversee proper delivery, receipt, and conduct of radiation surveys for all shipments of radioactive material arriving at or leaving from the institution, as well as packaging and labeling all radioactive material leaving the institution.
- Determine the need for personnel monitoring; distribute and collect personnel radiation monitoring devices, evaluate bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching the limits, and recommend appropriate remedial action.
- Conduct training programs and otherwise instruct personnel in the proper procedures for handling radioactive material prior to use, at periodic intervals (refresher training), and as required by changes in procedures, equipment, rules, etc.
- Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and record keeping on waste storage and disposal records.
- Oversee the storage of radioactive material not in current use, including waste.
- Perform or arrange for leak tests on all sealed sources and calibration of radiation survey instruments.
- Maintain an inventory of all radioisotopes possessed under the license and limit the quantity to the amounts authorized by the license.
- Immediately terminate any unsafe condition or activity that is found to be a threat to public health and safety or property.
- Supervise decontamination and recovery operations.
- Maintain other records not specifically designated above, for example, records of receipts, transfers, and surveys as required by **12VAC5-481-100**, **12VAC5-481-571**, **12VAC5-481-980** and **12VAC5-481-1000**.
- Hold periodic meetings with, and provide reports to, licensee management.
- Ensure that all users are properly trained.
- Perform annual audits of the radiation safety program to ensure that the licensee is complying with all applicable VDH requirements and the terms and conditions of the

license (e.g., leak tests, inventories, use limited to trained, approved users, etc.), the content and implementation of the radiation safety program to achieve occupational doses and doses to members of the public that are "ALARA" in accordance with **12VAC5-481-630** and required records are maintained.

- Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented (and maintained for at least 3 years) and provided to management for review; ensure that prompt action is taken to correct deficiencies.
- Ensure that the audit results and corrective actions are communicated to all personnel who use licensed material.
- Ensure that all incidents, accidents, and personnel exposure to radiation in excess of "ALARA" or **12VAC5-481-630**, **12VAC5-481-640** and **12VAC5-481-720** limits are investigated and reported to VDH and other appropriate authorities, if required, within the required time limits.
- Maintain understanding of and up-to-date copies of **12VAC5-481 'Virginia Radiation Protection Regulations'**, the license, revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to VDH during the licensing process.

Appendix J

Criteria for Acceptable Training for Authorized Users and Radiation Safety Officers

Criteria for Acceptable Training for Authorized Users and Radiation Safety Officers

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

Frequency of Training

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

General Information

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

Licensee-Specific Program Elements

- A. Authorized users and supervised users
- B. Ordering and receiving radioisotopes
- C. Applicable VDH requirements and license conditions
- D. Areas where radioactive material is used or stored
- E. Potential hazards associated with radioactive material in each area where the individuals will work

- F. Appropriate radiation safety procedures
- G. Licensee's in-house work rules. (For instructions on laboratory safety and uses of radioisotopes, see 'For Laboratory Safety and Use of Radioisotopes' below.)
- H. Each individual's obligation to report unsafe conditions to the RSO
- I. Appropriate response to spills, emergencies or other unsafe conditions
- J. Worker's right to be informed of occupational radiation exposure and bioassay results, if applicable
- K. Locations where the licensee has posted or made available: notices, copies of pertinent VDH rule, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by **12VAC5-481-2260**.
- L. Emergency procedures:
 - 1. RSO name and telephone number
 - 2. immediate steps to prevent or control spread of contamination
 - 3. clean-up instructions, decontamination.
- M. Survey program:
 - 1. survey instrument accessibility
 - 2. who is responsible
 - 3. types, contamination and area
 - 4. frequency
 - 5. levels of contamination
 - 6. personnel, hands, shoes
 - 7. records
- N. Waste
 - 1. liquid
 - 2. solids
 - 3. sanitary sewer
 - 4. burial (transfer to low level waste repository)
 - 5. storage
 - 6. decay-in-storage
 - 7. waste storage surveys
 - 8. incineration
 - 9. records
- O. Dosimetry
 - 1. whole body
 - 2. extremities
 - 3. lost or replacement badges and dose assessment
 - 4. bioassay procedures
 - 5. records
- P. Instrumentation
 - 1. survey meters-use, calibration frequency, use of check sources
 - 2. analytical instruments-gas chromatographs, liquid scintillation counters
- Q. Procedures for receiving packages containing radioactive materials
 - 1. normal
 - 2. off-duty
 - 3. notification of user and RSO
 - 4. security
 - 5. exposure levels
 - 6. possession limit
 - 7. receipt of damaged packages
- R. Procedures for opening and examining packages
 - 1. leakage and contamination

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

For Laboratory Safety and Use of Radioisotopes

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

Appendix K

Facilities and Equipment Considerations

Facilities and Equipment Considerations

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

- Restricted areas are defined as areas to which access is limited by the licensee to protect individuals against undue risks from exposure to radiation and radioactive materials. The application should contain detailed descriptions and diagrams of the facilities, including information about the shielding properties of the construction materials used. Scaled drawings and sketches should be submitted showing the relationship between restricted areas and unrestricted areas and the location of all pertinent safety-related equipment.
- Bench top or open work areas may be used for sealed sources, for small quantities of solid materials in a form not likely to become airborne or dispersed, and for small quantities of liquids of such low volatility as not to cause airborne contamination or toxicity problems. Trays and/or absorbent surface covers to catch and retain spilled liquids should be used on these open work surfaces and inside closed systems discussed below. Surfaces should be smooth and non-porous, to facilitate decontamination.
- Radioactive materials that are handled or used in unsealed forms should be confined to control the release of material and to prevent the spread of contamination. Gaseous, volatile, and fine particulate solid materials should be handled in closed or isolated systems such as fume hoods or glove boxes with controlled, and possibly filtered, exhaust systems.

Chemical-type fume hoods provide a working area with controlled inward airflow from the room to the hood exhaust system. Hoods are used for gases, for unsealed volatile licensed materials, and for processes such as evaporation that may release gases and vapors. Fume hoods provide emergency ventilation and exhaust for unplanned releases, such as accidental spills and ruptures, as well as routine exhaust of effluents. Filters may be required in the exhaust stream unless monitoring and/or calculations demonstrate that any planned or likely effluent will be in accordance with the limits found in **12VAC5-481-3690**. Glove boxes are sealed boxes with transparent viewing windows, seal-able ports or doors for transferring materials and equipment, and gloves sealed to the box through which licensed materials are handled. Glove boxes are used for the containment during storage and use of liquids and solids that can become airborne particulates or aerosols. Glove boxes can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.

- Sink faucets should be designed, where possible, for operation by foot, knee, or elbow rather than by hand.
- Plumbing and ductwork should be designed to avoid radioactive contamination build-up. This build-up of contamination can create external radiation exposure hazards and problems for decommissioning.
- Shielding consisting of lead or other high-density material in the form of bricks, panels, L-shields, storage containers, or other shapes may be used on bench tops, in fume hoods or in glove boxes to reduce radiation exposure from gamma-emitting radioactive materials. Similarly, shielding of low atomic number material, such as high-density plastic, may be used to reduce the exposure from high-energy beta-

emitting materials. Shielded shipping containers are frequently used for continued storage after receipt of materials.

- A particular sink should be designated for disposal of liquid radioactive waste to the sanitary sewerage system. In some cases, depending on number of users and distance between areas of use, more than one sink may need to be designated.
- Labeled waste containers should be used. These containers may be shielded as necessary, placed near the waste generating areas and away from areas frequently occupied by personnel. Additionally, these containers should be effectively enclosed to prevent airborne contamination from radioactive materials deposited.
- Remote handling tools, such as forceps or extension handles, should be used to provide distance in the handling of radioactive materials (ALARA). In addition, shielded handling devices, such as shielded syringes, can be used to protect workers from materials that cannot be handled remotely. Pipetting should be done using appropriate devices. Pipetting by mouth should be strictly forbidden.
- Where appropriate, ventilation systems should be designed such that, in the event of an accident, they can be shut down to prevent the spread of radioactivity.
- Designated areas should be provided for coats and personal belongings, to avoid contamination.
- Areas with background radiation levels should be designated for personnel dosimetry storage when not in use.
- Areas of use should be well lighted to avoid spills and other accidents that could result in contamination build-up.
- Observation of activities conducted behind shielding with remote tools (or with extended arms and hands, within limits consistent with permissible occupational exposures) can be accomplished by mirrors, through shielded (e.g., leaded glass) windows, through transparent plastic beta shields, or by remote video monitoring.
- The combination of containment, shielding, and handling devices proposed for any use of radioactive materials should be appropriate to the type and quantity of materials to be used and to the type and duration of operations to be conducted.
- If respiratory protective equipment will be used to limit inhalation of airborne licensed material, follow the provisions of **12VAC5-481-830**.
- If compaction of waste is performed, ensure that facilities are adequate for the ventilation of the area where the waste is compacted. In addition, also ensure that air sampling for internal exposures is available, if needed per **12VAC5-481-670**.

Appendix L

Sample Audit Program

Sample Audit Program

An audit is conducted, in part, to fulfill the requirements of **12VAC5-481-630** for an annual review of the content and implementation of the licensee's radiation protection program. It should also identify program weaknesses and allow licensees to take early corrective actions (before a VDH inspection). During an audit, the auditor needs to keep in mind not only the requirements of VDH but also the licensee's commitments in its applications and other correspondence with VDH. The auditor should also evaluate whether the licensee is maintaining exposures to workers and the general public as low as is reasonably achievable (ALARA) and, if not, make suggestions for improvement.

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

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

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

Section 3: Training, Retraining, and Instructions to Workers. Ensure that workers have received the training required by **12VAC5-481-2270**. Be sure that, before being permitted to use radioactive material, the user has received training and has a copy of the licensee's safe use and emergency procedures. Note whether refresher training is conducted in accordance with licensee commitments. Ensure that each worker has a copy of the licensee's procedures, and by interview and/or observation of selected workers that he/she can implement them.

Section 4: Audits. Verify that audits fulfill the requirements of **12VAC5-481-630**, are conducted in accordance with licensee commitments, and are properly documented.

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

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

Section 7: Leak Tests. Verify that all sealed/plated foil sources are tested for leakage at the prescribed frequency in accordance with **12VAC5-481-740**. Records of results should be maintained.

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

Section 9: Radiation Surveys. Verify that the licensee has appropriate, operable and calibrated survey instruments available, that the instruments are calibrated (at the required frequency) in accordance with license conditions and in accordance with **12VAC5-481-750**. Calibration records must be retained for 3 years after the record is made. Check that radiation levels in areas

adjacent to use are within regulatory limits and in accordance with **12VAC5-481-750**. Verify compliance with **12VAC5-481-720**. Records of surveys must be retained for 3 years after the record is made.

Section 10: Receipt and Transfer of Radioactive Material (Includes Waste Disposal). Verify that packages containing radioactive material, received from others, are received, opened, and surveyed in accordance with **12VAC5-481-900**. Ensure that transfers are performed in accordance with **12VAC5-481-570**. Records of surveys, receipt, and transfer must be maintained in accordance with **12VAC5-481-100** and **12VAC5-481-571**.

Section 11: Transportation. Determine compliance with United States Department of Transportation (DOT) requirements. Verify that radioactive packages are prepared, marked, and labeled in accordance with **12VAC5-481 'Virginia Radiation Protection Regulations', Part XIII 'Transportation of Radioactive Material'** requirements. Verify that shipping papers are prepared, that they contain all needed information, and that they are readily accessible during transport.

Section 12: Personnel Radiation Protection. Evaluate the licensee's determination that unmonitored personnel are not likely to receive more than 10 percent of the allowable limits. If personnel dosimetry is provided or required, verify that it complies with **12VAC5-481-760** and licensee commitments. Review personnel monitoring records; compare exposures of individuals doing similar work; determine reasons for significant differences in exposures. If any worker declared her pregnancy in writing, evaluate the licensee's compliance with **12VAC5-481-710**. Check whether records are maintained as required by **12VAC5-481-1040**.

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

Section 14: Notification and Reports. Check on the licensee's compliance with the notification and reporting requirements in **12VAC5-481-1090**, **12VAC5-481-1100**, **12VAC5-481-1150** and **12VAC5-481-1110**. Ensure that the licensee is aware of VDH telephone numbers: during normal business hours (7:30 a.m. until 4:30 p.m.) at (804) 864-8150, and after business hours to the State Emergency Operations Center (804) 674-2400 or (800) 468-8892.

Section 15: Posting and Labeling. Check for compliance with the posting and labeling requirements of **12VAC5-481-860** and **12VAC5-481-880**.

Section 16: Recordkeeping for Decommissioning. Check to determine compliance with **12VAC5-481-450 C**.

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

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

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

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

Section 21: Evaluation of Other Factors. Evaluate licensee management's involvement with the radiation safety program, whether the RSO has sufficient time to perform his/her duties, and whether the licensee has sufficient staff to handle the workload and maintain compliance with regulatory requirements.

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit.

Sample Audit Checklist

Audit Report No.: _____

License No.: _____

Date of this Audit: _____

Licensee's name and mailing address:

Audit of activities at (Address):

Contact at Audit Location: _____

Telephone No.: _____

Summary of Findings and Action:

No deficiencies

Deficiencies

Action on previous deficiencies

Recommendations:

Auditor: _____

(Signature)

Date: _____

1. AUDIT HISTORY

N/A (N/A means "Not applicable" - Initial Audit)

A. Last audit of this location conducted _____

B. Problems/deficiencies identified during last two audits or two years, whichever is longer

YES NO

C. Open problems/deficiencies from previous audits:

Status Requirement	Prob./Def.	Corrective Action Taken (Y/N)	Open/Closed
--------------------	------------	-------------------------------	-------------

D. Any previous problem/deficiency not corrected or repeated
Explain:

YES NO
N/A

2. ORGANIZATION AND SCOPE OF PROGRAM

A. Briefly describe organizational structure:

1. Structure is as described in license documents

YES NO

2. Multiple authorized locations of use

YES NO

3. Briefly describe scope of activities involving radioactive material, frequency of use, staff size, etc

B. Radiation Safety Officer

1. Authorized on license

YES NO

2. Fulfills duties as RSO

YES NO

C. Use only by authorized individuals

YES NO

Remarks:

3. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

A. Instructions to workers per 12VAC5-481-2270.

YES NO

B. Training program required

YES NO

C. Training records maintained

YES NO

D. Evaluation of individuals' understanding of procedures and rules based on interviews, observation of selected workers

YES NO

1. Each has an up-to-date copy of the licensee's safe use and emergency procedures

YES NO

2. Adequate understanding of:

a. Current safe use procedures

YES NO

b. Emergency procedures

YES NO

E. Workers cognizant of requirements for:

1. Radiation Safety Program (12VAC5-481-630).

YES NO

2. Annual dose limits (12VAC5-481-640).

YES NO

3. VDH Forms: 'Cumulative Occupational Exposure History' and 'Occupational Exposure Record for a Monitoring Period'

YES NO

4. 10% monitoring threshold (12VAC5-481-760).

YES NO

5. Dose limits to embryo/fetus and declared pregnant women (12VAC5-481-710).

YES NO

6. Procedures for opening packages (12VAC5-481-900).

YES NO

Remarks:

4. INTERNAL AUDITS, REVIEWS OR INSPECTIONS

A. Audits are conducted

YES NO

1. Audits conducted by _____

2. Frequency _____

B. Content and implementation of the radiation protection program reviewed annually (12VAC 5-481-630).

YES NO

C. Records maintained per 12VAC 5-481-990.

YES NO

5. FACILITIES

A. Facilities as described in license application YES NO
Remarks:

6. MATERIALS

A. Isotopes, quantities, and use as authorized on license YES NO
Remarks:

7. LEAK TESTS

A. Leak test performed as described in correspondence with VDH (consultant; leak test kit; licensee performed) YES NO
B. Frequency: every 6 months or other interval, as approved by the NRC or another Agreement State YES NO
C. Records with appropriate information maintained YES NO
Remarks:

8. INVENTORIES

A. Conducted at 6-month intervals YES NO
B. Records with appropriate information maintained YES NO
Remarks:

9. RADIATION SURVEYS

A. Instruments and Equipment:
1. Appropriate operable survey instrumentation possessed or readily available YES NO
2. Calibrated as required 12VAC5-481-750. YES NO
3. Calibration records maintained 12VAC5-481-1000 YES NO
B. Briefly describe survey requirements (12VAC5-481-750).
C. Performed as required (12VAC5-481-750).
1. Radiation levels within regulatory limits YES NO
2. Corrective action taken and documented YES NO
D. Records maintained (12VAC5-481-1000). YES NO
E. Protection of members of the public
1. Adequate surveys made to demonstrate either (a) that the TEDE to the individual likely to receive the highest dose does not exceed 100 mrem in a year, or (b) that if an individual were continuously present in an unrestricted area, the external dose would not exceed 2 mrem in any hour and 100 mrem in a year (12VAC5-481-720). YES NO
2. Unrestricted area radiation levels do not exceed 2 mrem in any one hour (12VAC5-481-720). YES NO
3. Records maintained (12VAC5-481-1050). YES NO
Remarks:

10. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL (INCLUDES WASTE DISPOSAL)

A. Procedures describe how packages are received and by whom. YES NO
B. Written package opening procedures established and followed (12VAC5-481-900 & 12VAC5-481-3091). YES NO
C. If package shows evidence of degradation, monitor for contamination and radiation levels YES NO
D. Monitoring of degraded packages performed within time specified (12VAC5-481-900). YES NO
E. Transfer(s) between licensees (including "disposal") performed per 12VAC5-481-570. YES NO
F. Records of receipt/transfer maintained (12VAC5-481-100 & 12VAC5-481-571). YES NO

G. Transfers within licensee's authorized users or locations performed as required [L/C]

YES NO

H. Package receipt/distribution activities evaluated for compliance with 12VAC5-481-900.

YES NO

Remarks:

11. TRANSPORTATION (12VAC5-481, Part XIII)

N/A

A. Licensee shipments are:

- 1. delivered to common carriers
- 2. transported in licensee's own private vehicle
- 3. no shipments since last audit

YES NO
 N/A
 YES NO
 N/A
 YES NO
 N/A

B. Packages

- 1. Authorized packages used [49 CFR 173.415 & 173.416(b)]
- 2. Closed and sealed during transport [49 CFR 173.475(f)]

N/A
 YES NO
 YES NO

C. Shipping Papers

- 1. Prepared and used [49 CFR 172.200(a)]
- 2. Proper {Shipping name, Hazard Class, UN Number, Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, Category of label, T1, Shipper's Name, Certification and Signature, Emergency Response Phone Number, "Cargo Aircraft Only" (if applicable)} [49 CFR 172.200-204]
- 3. Readily accessible during transport [49 CFR 177.718(e)]

N/A
 YES NO
 YES NO
 YES NO
 YES NO

D. Vehicles

- 1. Cargo blocked and braced [49 CFR 177.842(d)]
- 2. Placarded, if needed [49 CFR 172.504]
- 3. Proper overpacks, if used (shipping name, UN Number, labeled, statement indicating that inner package complies with specification package) [49 CFR 173.25]

YES NO
 YES NO
 YES NO
 YES NO
 YES NO

E. Any incidents reported to DOT [49 CFR 171.15 & 171.16]

Remarks:

12. PERSONNEL RADIATION PROTECTION

A. ALARA considerations are incorporated into the Radiation Protection Program (12VAC5-481-630).

YES NO

B. Adequate documentation of determination that unmonitored occupationally individuals are not likely to receive >10% of allowable limit (12VAC5-481-640).

YES NO
N/A

OR

C. External dosimetry provided and required

YES NO
N/A

- 1. Supplier _____ Frequency _____
- 2. Supplier is NVLAP-approved (12VAC5-481-750).
- 3. Dosimeters exchanged at required frequency [L/C]

YES NO
N/A

D. Occupational intake monitored and assessed (12VAC5-481-760).

N/A

E. Reports

N/A

- 1. Reviewed by _____ Frequency _____
- 2. Auditor reviewed personnel monitoring records for period _____ to _____
- 3. Prior dose determined for individuals likely to receive doses (12VAC5-481-680).
- 4. Maximum exposures TEDE Other
- 5. VDH Forms or equivalent (12VAC5-481-1040).

YES NO

- a. "Cumulative Occupational Exposure History" forms are maintained
- b. "Occupational Exposure Record for a Monitoring Period" forms are maintained

YES NO

- 6. Worker declared her pregnancy in writing during inspection period (review records)

If yes, determine compliance with 12VAC5-481-710.
Check for records per 12VAC5-481-1040.

YES NO
 YES NO
 N/A
 YES NO
 N/A
 YES NO
 N/A

- F. Records of exposures, surveys, monitoring, and evaluations maintained per 12VAC5-481-980, 12VAC5-481-1000, 12VAC5-481-1040 & 12VAC5-481-1080.

YES NO

- G. Annual exposure reports given to workers who receive > 100 mrem per year per 12VAC5-481-2280?

YES NO
N/A

Remarks:

13. AUDITOR'S INDEPENDENT MEASUREMENTS (IF MADE)

A. Survey instrument: Serial No.: Last calibration:

YES NO
N/A

- B. Auditor's measurements compared to licensee's

- A. Licensee in compliance with 12VAC5-481-2280. (reports to individuals, public and occupational, monitored to show compliance)

YES NO
N/A

- B. Licensee in compliance with 12VAC5-481-1090. (theft or loss)

YES NO
N/A

- C. Licensee in compliance with 12VAC5-481-1100 & 12VAC5-481-1110 (incidents)

YES NO
N/A

- D. Licensee in compliance with 12VAC5-481-1110. (overexposures and high radiation levels)

YES NO
N/A

- E. Licensee aware of telephone number for VDH: (804) 864-8150 from 7:45 a.m. - 4:30 p.m. and (804) 674-2400 or (800) 468-8892 for after hour radiological emergencies.

YES NO

15. POSTING AND LABELING

- A. "Notice to Employees" is posted per 12VAC5-481-2260 C.

YES NO

- B. 12VAC5-481 'Virginia Radiation Protection Regulations', Parts IV and X, License and Operating Procedures are posted, or a notice indicating where documents can be examined is posted per 12VAC5-481-2260 A & B.

YES NO

- C. Emergency procedures are posted per 12VAC5-481-2260 A.

YES NO

- D. Other posting and labeling per 12VAC5-481-860 & 12VAC5-481-880.

YES NO

Remarks:

16. RECORD KEEPING FOR DECOMMISSIONING (if needed)

N/A

- A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination per 12VAC5-481-450 C.

YES NO

- B. Records include all information outlined in 12VAC5-481-450 C.

YES NO

Remarks:

17. INFORMATION NOTICES

- A. Receipt of VDH Information Notices

YES NO

- B. Appropriate action taken in response to VDH Information Notices

YES NO

Remarks:

18. SPECIAL LICENSE CONDITIONS OR ISSUES

N/A

- A. Review special license conditions or other issues, and describe findings:

B. Problems/deficiencies identified at licensee facilities other than at audit location:

C. Evaluation of compliance:

19. CONTINUATION OF REPORT ITEMS

(If more space is needed, use separate sheets and attach to report.)

N/A

20. PROBLEMS OR DEFICIENCIES NOTED; RECOMMENDATIONS

Note: Briefly state (1) the requirement and (2) how and when violated. Provide recommendations for improvement.

N/A

21. EVALUATION OF OTHER FACTORS

A. Senior licensee management is appropriately involved with the radiation safety program and/or Radiation Safety Officer (RSO) oversight

YES NO

B. RSO has sufficient time to perform his/her radiation safety duties and is not too busy with other assignments

YES NO

C. Licensee has sufficient staff

YES NO

Remarks/recommendations:

Appendix M

Radiation Monitoring Instrument Specifications, Survey Instrument and Air Sampler Calibration Program

Radiation Monitoring Instrument Specifications, Survey Instrument and Air Sampler Calibration Program

Radiation Monitoring Instrument Specifications

The specifications in **Table 10** will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facilities.

Table 10: Typical Survey Instruments¹
(Instruments used to measure radiological conditions at licensed facilities.)

Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	Radiation	Energy Range	Efficiency
Exposure Rate Meters	Gamma, X-Ray	μR-R	N/A
Count Rate Meters			
GM	Alpha	All energies (dependent on window thickness)	Moderate
	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate
Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detectors	Radiation	Energy Range	Efficiency
LSC*	Alpha	All energies	High
	Beta	All energies	High
	Gamma		Moderate
Gamma Counter (NaI)*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

¹ Table from The Health Physics & Radiological Health Handbook, Revised Edition, Edited by Bernard Shleien, 1992 (except for * items).

Instrument Calibration Program

Training

Before allowing an individual to perform survey instrument calibrations, the RSO will ensure that he or she has sufficient training and experience to perform independent survey instrument calibrations.

Classroom training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection;

- Radioactivity measurements, monitoring techniques, and using instruments;
- Mathematics and calculations basic to using and measuring radioactivity; and
- Biological effects of radiation.

Appropriate on-the-job-training consists of the following:

- Observing authorized personnel performing survey instrument calibration; and
- Conducting survey meter calibrations under the supervision and in the physical presence of an individual authorized to perform calibrations.

Facilities and Equipment for Calibration of Dose Rate or Exposure Rate Instruments

- To reduce doses received by individuals not calibrating instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present.
- Individuals conducting calibrations will wear assigned dosimetry.
- Individuals conducting calibrations will use a calibrated and operable survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Procedure for Calibrating Survey Instruments

A radioactive sealed source(s) used for calibrating survey instruments will:

- Approximate a point source;
- Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified by National Institutes of Standards and Technology (NIST);
- Approximate the same energy and type of radiation as the environment in which the calibrated device will be employed; and
- For dose rate and exposure rate instruments, the source should be strong enough to give an exposure rate of at least about 7.7×10^{-6} coulombs/kilogram/hour (30 mR/hr) at 100 cm [e.g., 3.1 gigabecquerels (85 mCi) of Cs-137 or 7.8×10^2 megabecquerels (21 mCi) of Co-60].

The three kinds of scales frequently used on dose or dose rate survey meters are calibrated as follows:

- Linear readout instruments with a single calibration control for all scales shall be adjusted at the point recommended by the manufacturer or at a point within the normal range of use. Instruments with calibration controls for each scale shall be adjusted on each scale. After adjustment, the response of the instrument shall be checked at approximately 20% and 80% of full scale. The instrument's readings shall be within $\pm 15\%$ of the conventionally true values for the lower point and $\pm 10\%$ for the upper point;
- Logarithmic readout instruments, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. The instrument shall be adjusted for each scale according to site specifications or the manufacturer's specifications. After adjustment, calibration shall be checked at a minimum of one point on each decade. Instrument readings shall have a maximum deviation from the conventionally true value of no more than 10% of the full decade value;
- Meters with a digital display device shall be calibrated the same as meters with a linear scale;

- Readings above 2.58×10^{-4} coulomb/kilogram/hour (1 R/hr) need not be calibrated, but such scales should be checked for operation and response to radiation; and
- The inverse square and radioactive decay law should be used to correct changes in exposure rate due to changes in distance or source decay.

Surface Contamination Measurement Instruments

- Survey meters' efficiency must be determined by using radiation sources with similar energies and types of radiation that the survey instrument will be used to measure.
- If each scale has a calibration potentiometer, the reading shall be adjusted to read the conventionally true value at approximately 80% of full scale, and the reading at approximately 20% of full scale shall be observed. If only one calibration potentiometer is available, the reading shall be adjusted at mid-scale on one of the scales, and readings on the other scales shall be observed. Readings shall be within 20% of the conventionally true value.

Procedures for Calibrating, Liquid Scintillation Counters, Gamma Counters, Gas Flow Proportional Counters, and Multichannel Analyzers

A radioactive sealed source used for calibrating instruments will do the following:

- Approximate the geometry of the samples to be analyzed;
- Have its apparent source activity traceable by documented measurements to a standard certified by National Institutes of Standards and Technology (NIST); and
- Approximate the same energy and type of radiation as the samples that the calibrated device will be used to measure.

Calibration

- Calibration must produce readings within ± 20 per cent of the actual values over the range of the instrument.
- Calibration of liquid scintillation counters will include quench correction.

Calibration Records

Calibration records, for all survey instruments, should indicate the procedure used and the data obtained.

The description of the calibration should include:

- The owner or user of the instrument;
- A description of the instrument, including the manufacturer's name, model number, serial number, and type of detector;
- A description of the calibration source, including the exposure rate at a specified distance or activity on a specified date;
- For each calibration point, the calculated exposure rate or count rate, the indicated exposure rate or count rate, the deduced correction factor (the calculated exposure rate or count rate divided by the indicated exposure rate or count rate), and the scale selected on the instrument;
- For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular);

- For instruments with internal detectors, the angle between radiation flux field and a specified surface of the instrument;
- For detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure;
- The exposure rate or count rate from a check source, if used; and
- The name of the person who performed the calibration and the date it was performed.

The following information should be attached to the instrument as a calibration sticker or tag:

- For exposure rate meters, the source isotope used to calibrate the instrument (with correction factors) for each scale;
- The efficiency of the instrument, for each isotope the instrument will be used to measure (if efficiency is not calculated before each use);
- For each scale or decade not calibrated, an indication that the scale or decade was checked only for function but not calibrated;
- The date of calibration and the next calibration due date; and
- The apparent exposure rate or count rate from the check source, if used.

Air Sampler Calibration

In order to assess accurately the air concentration of radioactive materials in a given location, the volume of air sampled and the quantity of contaminant in the sample must be determined. Accurate determination of the volume of air sampled requires standard, reproducible, and periodic calibration of the air metering devices that are used with air sampling instruments.

The publication entitled '*Air Sampling Instruments*' found in the 7th Edition, American Conference of Governmental Industrial Hygienists, 1989, provides guidance on total air sample volume calibration methods acceptable to VDH staff, as supplemented below.

Frequency of Calibration

- A licensee committed to a routine or emergency air sampling program should perform an acceptable calibration of all airflow or volume metering devices at least annually (See NRC Regulatory Guide 8.25).
- Special calibrations should be performed at any time there is reason to believe that the operating characteristics of a metering device have been changed, by repair or alteration, or whenever system performance is observed to have changed significantly.
- Routine instrument maintenance should be performed as recommended by the manufacturer.
- Primary or secondary standard instruments used to calibrate air sampling instruments should be inspected frequently for consistency of performance.

Error Limit For Measurement of Air Sample Volume

Most methods of calibrating airflow or air volume metering devices require direct comparison to a primary or secondary standard instrument, to determine a calibration curve or a correction factor. An example of a primary standard is a spirometer that measures total air volume directly with high precision by liquid displacement. An example of a secondary standard is a wet-test meter that has been calibrated against a primary standard. Primary standards are usually accurate to within $\pm 1\%$ and secondary standards to within $\pm 2\%$.

The following are significant errors associated with determining the total air volume sampled:

- E_C : The error in determining the calibration factor. (An acceptable estimate is the percentage error associated with the standard instrument used in the calibration.)
- E_S : Intrinsic error in reading the meter scale. (An acceptable estimate is the percentage equivalent of one-half of the smallest scale division, compared to the scale reading.)
- E_t : The percentage error in measurement of sampling time that should be kept within 1%.
- E_V : The most probable value of the cumulative percentage error in the determination of the total air volume sampled.
- E_V : can be calculated from the following equation, provided there are no additional significant sources of errors:

$$E_V = [E_S^2 + E_C^2 + E_t^2]^{1/2}$$

The most probable value of the cumulative error E_V , in the determination of total volume, should be less than 20%.

A sample calculation of the most probable value of the cumulative error in total volume measured is as follows: If accuracies of the scale reading, the calibration factor, and sample time are ± 4 , 2, and 1 %, respectively, and there are no other significant sources of error, the cumulative error would be:

$$E_V = [4^2 + 2^2 + 1^2]^{1/2} = 4.58\% \text{ or approx. } 5\%$$

If there are significant differences in pressure and temperature between the calibration site and the sampling site, appropriate corrections should be made using the ideal gas laws provided below:

$$V_s = V_1 * (P_1/760) * (273/T_1)$$

Where V_s = volume at standard conditions (760 mm & 0^o C)

V_1 = volume measured at conditions P_1 and T_1

T_1 = temperature of V_1 in ^oK

P_1 = pressure of V_1 in mm Hg

Documentation of Calibration of Air Metering Devices

The licensee should maintain records of all routine and special calibrations of airflow or volume metering devices, including the primary or secondary standard used, method employed, and estimates of accuracy of the calibrated metering devices. All instruments should be clearly labeled as to the date and results of the most recent calibration and should include the appropriate correction factors to be used.

References:

- NRC Regulatory Guide 8.25, Revision 1, 'Air Sampling in the Workplace', which can be accessed at the NRC web site at www.nrc.gov.
- NRC NUREG - 1400, 'Air Sampling in the Workplace', which can be accessed at the NRC website at www.nrc.gov.
- The Health Physics & Radiological Health Handbook, Revised Edition, Edited by Bernard Shleien
- ANSI N323A-1997, 'Radiation Protection Instrumentation Test and Calibration.' Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018 or ordered electronically at the following address: <http://www.ansi.org>.
- 'Air Sampling Instruments,' American Conference of Governmental Industrial Hygienists, 1987

Appendix N

Material Receipt and Accountability

Material Receipt and Accountability

Sample Procedure for Ordering and Receiving Radioactive Material

- The RSO should approve or place all orders for radioactive material and should ensure that the requested material, quantities, manufacturer, and model are authorized by the license and that the possession limits are not exceeded.
- During normal working hours, carriers should be instructed to deliver radioactive packages directly to the Radiation Safety Office (or designated receiving area).
- During off-duty hours, security or other designated trained personnel should accept delivery of radioactive packages in accordance with the procedure outlined in the sample memorandum below:

Sample Memorandum

Memorandum for Security Personnel

From: RSO, President, Vice President, etc.

Subject: Procedures for Receipt of Packages Containing Radioactive Material

If the package appears to be damaged, immediately contact the RSO. Ask the carrier to remain at the facility until it can be determined that neither the carrier nor the vehicle is contaminated.

Any packages containing radioactive material that arrive between (state times, e.g., 4:30 p.m. and 7:00 a.m. or on Saturdays or Sundays) shall be signed for by the security guard (or other designated trained individual) on duty and taken immediately to the designated receiving area. Security personnel (or other designated trained individual) should unlock the door, place the package in the designated secured storage area and re-lock the door.

Radiation Safety Officer (RSO): _____

Office Phone: _____

Home Phone: _____

Sample Instructions to Personnel Involved in Material Receipt

Shipping and Receiving Personnel

During normal working hours, immediately upon receipt of any package of licensed material, each package must be visually inspected for any signs of shipping damage such as crushed or punctured containers or signs of dampness. Any obvious damage must be reported to the RSO immediately. Do not touch any package suspected of leaking. Request the person delivering the package to remain until monitored by the RSO.

Outside of normal working hours (e.g., nights, weekends, and holidays), deliveries will usually be handled by security personnel (or other trained individuals) as described in the above procedures. Since certain packages of licensed material will have detectable external radiation, they should be sent immediately to a designated storage area, where they will be checked for contamination and external radiation level as soon as practical. They should not be allowed to remain in the receiving area any longer than necessary, as they may be a source of exposure for receiving personnel.

If the instructions are not clear, or if there are questions regarding receiving packages containing radioactive material, please contact:

Name _____

Phone _____

For additional information on worker training, see Item 7 "Training for Individuals Working In or Frequenting Restricted Areas".

Sample Procedure for Safely Opening Packages Containing Licensed Materials

For packages received under the specific license, authorized individuals shall implement procedures for opening each package, as follows:

- Wear gloves to prevent hand contamination;
- Visually inspect the package for any sign of damage (e.g. crushed, punctured). If damage is noted, stop and notify the RSO;
- Check DOT White I, Yellow II, or Yellow III label or packing slip for activity of contents, so shipment does not exceed license possession limits;
- Monitor the external surfaces of a labeled package according to specifications in **Table 5**;
- Open the outer package (following supplier's directions if provided) and remove packing slip. Open inner package to verify contents (compare requisition, packing slip and label on the bottle or other container). Check integrity of the final source container (e.g., inspecting for breakage of seals or vials, loss of liquid, discoloration of packaging material, high count rate on smear). Again check that the shipment does not exceed license possession limits. If you find anything other than expected, stop and notify the RSO;
- Survey the packing material and packages for contamination before discarding. If contamination is found, treat as radioactive waste. If no contamination is found, obliterate the radiation labels prior to discarding in the regular trash;
- Maintain records of receipt, package survey, and wipe test results; and
- Notify the final carrier, and by telephone or facsimile, VDH when removable radioactive surface contamination exceeds the limits of **49 CFR 173.44**; or external radiation levels exceed the limits of **12VAC5-481-3080**.

Sample Transfer Policy Statements

Internal Transfers

Licensed materials that may be transferred from one department or laboratory or AU's control to another should have prior approval from the RSO. A written transfer procedure should be developed by the RSO to ensure that transfers are done in accordance with the conditions of the license. All transfers shall be done in a way that minimizes the probability of spillage or breakage. Double containers should be used, including suitable shielding, for such transfers.

External Transfers

Licensed material shall not be transferred or shipped from one institution to another without the approval of the RSO. Such transfers/shipments must be packaged and labeled in accordance with VDH, DOT, or U.S. Postal Service rules and regulations, whichever is applicable.

Gifts

On occasion, licensees may be offered or have donated licensed materials by other individuals as gifts (e.g., a retiring medical practitioner donating his cesium needles to the university medical center). All such gifts of radioactive materials must be transferred to the licensee and handled in accordance with VDH requirements and the conditions of the license. In any case, the RSO should approve the gift prior to the transfer.

Appendix O

Public Dose

Public Dose

This appendix describes methods for determining radiation doses to members of the public.

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 millisievert (mSv) [100 millirem (mrem)] in one calendar year resulting from the licensee's possession and/or use of licensed materials.
- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.

Members of the public include persons who live, work, study, or may be near locations where radioactive material is used or stored and employees whose assigned duties do not include the use of radioactive material but may work in the vicinity where such materials are used or stored.

Doses to Members of the Public

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

DOES NOT INCLUDE doses from:

- Sanitary sewerage discharges from licensees
- Natural background radiation
- Medical administration of radioactive material
- Voluntary participation in medical research

Typical unrestricted areas may include offices, shops, laboratories (where licensed material is not used or stored), areas outside buildings, property, and storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials, but the licensee may control access to these areas for other reasons, such as security.

The licensee may show compliance with the annual dose limit for individual members of the public by:

- Demonstrating by measurement or calculation that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv (100 mrem);
- Demonstrating that the annual average concentration of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area does not exceed the values specified in 12VAC5-481-3690, and if an individual were continuously present in an unrestricted area the dose from external sources would not exceed 0.02 mSv (2 mrem) in an hour and 0.5 mSv (0.05 rem) in a year; and
- Demonstrating that air emissions of radioactive materials do not result in doses greater than the constraint limit of 0.1 mSv (10 mrem) TEDE.

In order to perform a dose assessment, licensees should identify all potential sources of external and internal radiation exposure to members of the public and all locations of use, transport, and storage of radioactive material at their facilities. Licensees must then take radiation measurements or perform calculations to demonstrate compliance.

Measurements

The licensee may use measurements to demonstrate that the average annual releases are within regulatory limits, as well as to demonstrate that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv (100 mrem). These measurements may include:

- Dose rate surveys for radiation exposures from external radiation sources; and
- Measurements of radionuclides in air and water effluent.

The method used to measure dose will depend upon the nature of the radiation source. If the source of radiation is constant, it may be adequate to measure the dose rate and integrate it over time. If the source of radiation differs or changes over time, it may be necessary to perform continuous measurements.

Radioactivity releases may be determined by effluent monitoring or by effluent sampling and analysis. Airborne effluents may be discharged when volatile materials are used, such as during iodinations, but the discharge itself is usually not continuous since volatile materials are often used periodically rather than continuously. Liquid effluents may be discharged continuously or may be stored and subsequently discharged on a batch basis. For each type of source and for each route of potential exposure, consider the location of measurement points, whether continuous or periodic monitoring is required, the frequency of sampling and measurement, and any additional information. For discharges of airborne radionuclides, for example, it may be necessary to obtain information on the efficiency of filters and the air flow rate of the discharge system, as well as meteorological data and the distance to the nearest individual member of the public.

Calculation Method

Using a calculation method, the licensee must determine the highest dose an individual is likely to receive at the boundary of the unrestricted area. The licensee must take into account the individual's exposure from external sources and the concentration of radionuclides in gaseous and liquid releases. In practice, the licensee may wish to make conservative assumptions to simplify the dose calculation.

The public dose limit applies to the individual who is likely to receive the highest dose from licensed operations. Therefore, the dose calculations must consider the location with the potential for the highest internal and external exposures. A conservative calculation should assume that the individual was continuously present 24 hours a day, 365 days a year, or an occupancy factor of 1 (see **Table 11**). If the result of the calculation using an occupancy factor of 1 demonstrates that the public dose limit is not exceeded, then there is no need for further evaluation.

If the calculation demonstrates that the public dose limit is exceeded with an occupancy factor of 1, then more realistic assumptions of the individual's occupancy at the points of highest internal and external exposures may be made. The licensee may use the occupancy factors in **Table 11**

or may calculate a specific occupancy factor by determining the likely fraction of time that the individual is present.

Table 11: Standard Occupancy Factors

Occupancy Factor	Description
1	Work areas such as offices, laboratories, shops, and occupied space in nearby buildings or outdoor areas
1/4	Corridors, lounges, elevators using operators, unattended parking lots
1/16	Waiting rooms, rest rooms, stairways, unattended elevators, janitor's closets, outside areas used only for pedestrians or vehicular traffic

Records

The licensee must maintain records to demonstrate compliance with the dose limit for individual members of the public until VDH terminates the license. In general, survey and monitoring records of ambient radiation and effluent radioactivity should be adequate.

Records demonstrating the dose to an individual member of the public should identify the instruments used in the survey, the name of the surveyor, the date of the survey, the location of the survey(s) including a description or drawing of the area surveyed, survey results, and if applicable, the occupancy factors used and justification for their use. In addition, records demonstrating the dose to an individual member of the public that involve effluent sampling analysis should include information on concentrations of specific radionuclides, minimum detectable activity of the system and the estimated uncertainty of measurements.

Appendix P

General Topics for Safe Use of Radioisotopes and Model Emergency Procedures

**General Topics for Safe Use of Radioisotopes
and Model Emergency Procedures**

General Topics for Safe Use of Radioisotopes

Each laboratory or area where radioactive material is used or stored should have general rules, so that workers know what is required. Typical instructions should include:

- Wear a laboratory coat or other protective clothing at all times in areas where licensed materials are used;
- Wear disposable gloves at all times when handling licensed materials;
- After each procedure or before leaving the area, monitor hands, shoes, and clothing for contamination in a low-background area;
- Do not eat, drink, smoke or apply cosmetics in any area where licensed material is stored or used;
- Do not store food, drink or personal effects in areas where licensed material is stored or used
- Wear personnel monitoring devices, if required, at all times while in areas where licensed materials are used or stored;
- Dispose of radioactive waste only in designated, labeled and properly shielded receptacles;
- Never pipette by mouth;
- Store radioactive solutions in clearly labeled containers; and
- Secure all licensed material when it is not under the constant surveillance and immediate control of the user(s).

Storage of Food and Drink

Food or drink shall not be stored in refrigerators with radioisotopes.

Radionuclides-specific Procedures

Licenseses should develop written procedures for use of different radionuclides so that users know the types of shielding, protective clothing, survey instruments, surveys, and decontamination activities that are required. Examples of such procedures are included below.

Example 1:

If requesting more than 37 MBq (1 mCi) of iodine-125 or iodine-131, special safety instructions should be provided to users, including the following:

- A mandatory radiation survey and wipe test for radioactive contamination after each use;
- Bioassay procedures for individuals working with millicurie quantities of radioiodine;
- The use of vented hoods for iodination and for the storage of millicurie quantities of radioiodine;
- A dry run prior to the performance of unfamiliar procedures, in order to preclude unexpected complications. In addition, it is recommended that the RSO be present during new procedures; and
- Procedures for measuring the concentration of radioiodine effluents from the hoods.

Example 2:

If requesting more than 37 MBq (1 mCi) of phosphorus-32, special safety instructions should be provided to users, including the following:

- The use of low-density plastic shielding in order to keep bremsstrahlung radiation to a minimum;
- A mandatory radiation survey and wipe test for radioactive contamination after each use;
- The use of extremity monitors for procedures that involve one millicurie or more;
- A dry run prior to the performance of unfamiliar procedures in order to preclude unexpected complications. In addition, it is recommended that the RSO be present during new procedures; and
- The use of eye protection for procedures that involve 10 millicuries or more.

Model Procedures for Handling Emergencies

Appropriate first aid and other immediate medical needs of injured individuals should not be neglected, delayed, or ignored due to suspected contamination.

General Safety Procedures to Handle Spills

- Name and telephone number of RSO or an alternate person(s) should be posted conspicuously in areas of use, so that it is readily available to workers in case of emergencies. Licensee should have emergency equipment readily available for handling spills. Spill kits should include the following:
 - Disposable gloves;
 - Housekeeping gloves;
 - Disposable lab coats;
 - Disposable head coverings;
 - Disposable shoe covers;
 - Roll of absorbent paper with plastic backing;
 - Masking tape;
 - Plastic trash bags with twist ties;
 - "Radioactive Material" labeling tape;
 - Marking pen;
 - Pre-strung "Radioactive Material" labeling tags;
 - Box of Wipes;
 - Instructions for "Emergency Procedures";
 - Clipboard with a copy of the Radioactive Spill Report Form for the facility;
 - Pencil; and
 - Appropriate survey instruments including batteries (for survey meters).

Minor Spills of Liquids and Solids

- Instructions to Workers
 - Notify persons in the area that a spill has occurred.
 - Prevent the spread of contamination by covering the spill with absorbent paper. (Paper should be dampened if solids are spilled).
 - Clean up the spill, wearing disposable gloves and using absorbent paper.
 - Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Put contaminated gloves and any other contaminated disposable material in the bag.
 - Survey the area with an appropriate low-range radiation detector survey meter or other appropriate technique. Check the area around the spill for contamination. Also check hands, clothing, and shoes for contamination.
 - Report the incident to the Radiation Safety Officer (RSO) promptly.
 - Allow no one to return to work in the area unless approved by the RSO.
 - Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples).
 - Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).
- Reminders to RSO
 - Follow up on the decontamination activities and document the results;
 - As appropriate, determine cause and corrective actions needed; consider bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin; and
 - If necessary, notify VDH.

Major Spills of Liquids and Solids

- Instructions to Workers
 - Clear the area. If appropriate, survey all persons not involved in the spill and vacate the room;
 - Prevent the spread of contamination by covering the spill with absorbent paper (paper should be dampened if solids are spilled), but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated;
 - Shield the source only if it can be done without further contamination or significant increase in radiation exposure;
 - Close the room and lock or otherwise secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred;
 - Notify the RSO immediately;
 - Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with a mild soap;
 - Allow no one to return to work in the area unless approved by the RSO;
 - Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples); and
 - Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO
 - Confirm decontamination of personnel. If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration;
 - Supervise decontamination activities and document the results. Documentation should include location of surveys and decontamination results;
 - Determine cause and needed corrective actions; consider need for bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin; and
 - If necessary, notify VDH.

Incidents Involving Radioactive Dusts, Mists, Fumes, Organic Vapors, and Gases

- Instructions to Workers
 - Notify all personnel to vacate the room immediately;
 - Shut down ventilation system, if appropriate, to prevent the spread of contamination throughout system and other parts of facility;
 - Vacate the room. Seal the area, if possible;
 - Notify the RSO immediately;
 - Ensure that all access doors to the area are closed and posted with radiation warning signs, or post guards (trained) at all access doors to prevent accidental opening of the doors or entry to the area;
 - Survey all persons who could have possibly been contaminated. Decontaminate as directed by the RSO;
 - Promptly report suspected inhalations and ingestions of licensed material to the RSO;
 - Decontaminate the area only when advised and/or supervised by the RSO;
 - Allow no one to return to work in the area unless approved by the RSO;
 - Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples); and
 - Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision and collection of bioassay samples, requested documentation).
- Reminders to RSO
 - Supervise decontamination activities;
 - Perform air sample surveys in the area before permitting resumption of work with licensed materials;
 - Provide written directions to potentially contaminated individuals about providing and collecting urine, breath, blood, or fecal samples, etc;
 - Consider need for medical exam and/or whole body count before permitting involved individuals to return to work with licensed material;
 - Determine cause and corrective actions needed; consider need for bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin.
 - Document incident; and
 - If necessary, notify VDH.

Minor Fires

- Instructions to Workers
 - Immediately attempt to put out the fire by approved methods (i.e., fire extinguisher) if other fire hazards or radiation hazards are not present;
 - Notify all persons present to vacate the area and have one individual immediately call the RSO and fire department (as instructed by RSO);
 - Once the fire is out, isolate the area to prevent the spread of possible contamination;
 - Survey all persons involved in combating the fire for possible contamination;
 - Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with a mild soap;
 - In consultation with the RSO, determine a plan of decontamination and the types of protective devices and survey equipment that will be necessary to decontaminate the area;
 - Allow no one to return to work in the area unless approved by the RSO;
 - Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples); and
 - Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO
 - Supervise decontamination activities;
 - If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration;
 - Consult with fire safety officials to assure that there are no other possibilities of another fire starting;
 - Determine cause and needed corrective actions; consider need for bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin.
 - Document incident; and
 - If necessary, notify VDH.

Fires, Explosions, or Major Emergencies

- Instructions to Workers
 - Notify all persons in the area to leave immediately;
 - Notify the fire department;
 - Notify the RSO and other facility safety personnel;
 - Upon arrival of firefighters, inform them where radioactive materials are stored or where radioisotopes were being used; inform them of the present location of the licensed material and the best possible entrance route to the radiation area, as well as any precautions to avoid exposure or risk of creating radioactive contamination by use of high pressure water, etc;
 - Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples);
 - Allow no one to return to work in the area unless approved by the RSO; and
 - Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO
 - Coordinate activities with facility's industrial hygienist or environmental health & safety office, and with local fire department;
 - Consult with the firefighting personnel and set up a controlled area where the firefighters can be surveyed for contamination of their protective clothing and equipment after the fire is extinguished;
 - Once the fire is extinguished, do not allow the firefighters to enter the radiation area until a thorough evaluation and survey are performed to determine the extent of the damage to the licensed material use and storage areas;
 - Perform thorough contamination surveys of the firefighters and their equipment before they leave the controlled area and decontaminate, if necessary;
 - Supervise decontamination activities;
 - Consider bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin.
 - Document incident; and
 - If necessary, notify VDH.

Note: The telephone number for VDH during normal business hours (7:45 a.m. - 4:30 p.m.) is **(804) 864-8150**. After normal business hours, the emergency telephone numbers are **(804) 674-2400** or **(800) 468-8892**. Indicate radiological emergency.

Copies of emergency procedures must be provided to all users. Post a current copy in each laboratory or other area where radioactive material is used.

Appendix Q

Radiation Safety Survey Topics

Radiation Safety Survey Topics

This Appendix provides applicants and licensees with additional information on surveys, including training requirements, survey frequency, contamination limits, and bioassays.

Training

Before allowing an individual to perform surveys, the RSO will ensure that he or she has sufficient training and experience to perform surveys independently.

Academic training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection;
- Radioactivity measurements, monitoring techniques, and using instruments;
- Mathematics and calculations basic to using and measuring radioactivity; and
- Biological effects of radiation.

Appropriate on-the-job-training consists of the following:

- Observing authorized personnel using survey equipment, collecting samples, and analyzing samples; and
- Using survey equipment, collecting samples, and analyzing samples under the supervision and in the physical presence of an individual authorized to perform surveys.

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, survey samples will be analyzed in a low-background area.
- A gamma counter system with a single or multi-channel analyzer can be used to count samples containing gamma-emitters (e.g., Cs-137, Co-60).
- A liquid scintillation or gas-flow proportional counting system can be used to count samples containing alpha-emitters, beta-emitters, and gamma-emitters (if efficiency is great enough to achieve the required sensitivity for measurements).

Ambient Radiation Level Surveys

- Dose-rate surveys, at a minimum, should be performed in locations where workers are exposed to radiation levels that might result in radiation doses in excess of 10% of the occupational dose limits or where an individual is working in a dose rate of 0.025 mSv (2.5 mrem/hr) or more (50 mSv/year divided by 2,000 hr/year).
- **12VAC5-481-720** requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year and the dose in any unrestricted area from external sources does not exceed 0.02 mSv (2 mrem) in any one hour.

The frequency of ambient surveys depends on the quantity and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect the worker and members of the public from external exposure to radiation. While the rule does not specify a specific survey frequency, the licensee is required to ensure that the dose rate limits are not exceeded.

Contamination Surveys

Licensees' contamination surveys should be sufficient to identify areas of contamination that might result in doses to workers or to the public. Combined removable and fixed contamination should be surveyed using appropriate radiation detection equipment. Removable contamination can be detected and measured through a wipe test of the surface, which is counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

Contamination surveys should be performed:

- To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment;
- After any spill or contamination event;
- When procedures or processes have changed;
- To evaluate the potential contamination of users and the immediate work area, at the end of the day or prior to leaving the area of use, when licensed material is used;
- In unrestricted areas at frequencies consistent with the types and quantities of materials in use but generally not less frequently than quarterly; and
- In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.

Contamination Survey Frequency

Personnel should survey for contamination in locations where individuals are working with an unsealed form of radioactive material. These surveys should be done at a frequency appropriate to the types and quantities of radioactive materials in use. If the activity used is greater than or equal to the smallest annual limit on intake (ALI) (for either inhalation or ingestion) as identified in **12VAC5-481-3690**, then documented surveys should be performed at least daily in accordance with **12VAC5-481-750**.

Table 11 contains suggested contamination survey frequencies based on ALIs. The suggested frequency of surveys is based upon the amount of licensed material "in use" at any one time at any particular location. If licensed material has not been used for a period of time greater than the required survey frequency, then it is considered to be "not in use."

Table 12: Suggested Contamination Survey Frequency

	< 0.1 ALI	> 0.1 ALI < 1.0	≥ 1.0 ALI
In Use	Monthly	Weekly	Daily
Not in Use	Every 6 Months		

Contamination in Unrestricted Areas

Contamination found in unrestricted areas should be immediately decontaminated to background levels. When it is not possible to get to background levels, the licensee must ensure that the amounts do not exceed the contamination levels listed in **Table 13**

Table 13: Acceptable Surface Contamination Levels for Equipment

Nuclide ^a	Average ^{b, c}	Maximum ^{b, d}	Removable ^{b, e}
I-125, I-129	1.7 Bq*/100 cm ² (100 dpm/100 cm ²)	5.0 Bq/100 cm ² (300 dpm/100 cm ²)	0.3 Bq/100 cm ² (20 dpm/100 cm ²)
I-126, I-131, I-133, Sr-90	16.7 Bq/100cm ² (1,000 dpm/100 cm ²)	50.0 Bq/100cm ² (3,000 dpm/100 cm ²)	3.3 Bq/100cm ² (200 dpm/100 cm ²)
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	83.3 Bq*/100 cm ² (5,000 dpm/100 cm ²)	250 Bq/100 cm ² (15,000 dpm /100 cm ²)	16.7 Bq/100 cm ² (1,000 dpm/100 cm ²)

^a Where surface contamination by both alpha- and beta-gamma-emitting nuclides exists, the limits established for alpha- and beta-gamma-emitting nuclides should apply independently.

^b As used in this table, dpm (disintegration per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

^c Measurements of average contaminant should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.

^d The maximum contamination level applies to an area of not more than 100 cm².

^e The amount of removable radioactive material per 100 cm² of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

* 1 Bq = 1 Disintegration per second

When equipment or facilities that are potentially contaminated are to be released for unrestricted use, **Table 13** provides the maximum acceptable residual levels for equipment and **Table 14** provides screening values for building surface contamination. To the extent practicable, it is appropriate to decontaminate to below these levels. Surface contamination surveys should be conducted for both removable and fixed contamination before these facilities or equipment are released from restricted to unrestricted use, to ensure that they meet these limits.

A standardized method for smear testing of a relatively uniform area should be used to aid in comparing contamination at different times and places. A smear taken from an area of about 100 cm² is acceptable to indicate levels of removable contamination.

Table 14: Screening Values for Building Surface Contamination¹

Radionuclide	Symbol	Screening levels for unrestricted release (dpm/100 cm ²)
Hydrogen-3 (Tritium)	H-3	1.2 x 10 ⁸
Carbon-14	C-14	3.7 x 10 ⁶
Sodium-22	Na-22	9.5 x 10 ³
Sulfur-35	S-35	1.3 x 10 ⁷
Chlorine-36	Cl-36	5.0 x 10 ⁵
Manganese-54	Mn-54	3.2 x 10 ⁴
Iron-55	Fe-55	4.5 x 10 ⁶
Cobalt-60	Co-60	7.1 x 10 ³
Nickel-63	Ni-63	1.8 x 10 ⁶
Strontium-90	Sr-90	8.7 x 10 ³
Technetium-99	Tc-99	1.3 x 10 ⁶
Iodine-129	I-129	3.5 x 10 ⁴
Cesium-137	Cs-137	2.8 x 10 ⁴
Iridium-192	Ir-192	7.4 x 10 ⁴

¹ Screening levels are based on the assumption that the fraction of removable surface contamination is equal to 0.1. For cases when the fraction of removable contamination is undetermined or higher than 0.1, users may assume, for screening purposes, that 100% of surface contamination is removable; and therefore the screening levels should be decreased by a factor of 10. Alternatively, users having site-specific data on the fraction of removable contamination (e.g., within 10% to 100% range) may calculate site-specific screening levels using DandD Version 1.

Table 14 does not include screening values for radionuclides that emit alpha particles or for soil contamination. For such sites, licensees are encouraged to use, in the interim period, site-specific dose assessment based on actual site physical and environmental conditions.

Units are disintegrations per minute per 100 square centimeters (dpm/100 cm²). 1 dpm is equivalent to 0.0167 becquerel (Bq). The screening values represent surface concentrations of individual radionuclides that would be deemed in compliance with the 0.25 mSv/yr (25 mrem/yr) unrestricted release dose limit in **12VAC5-481-1161**. For radionuclides in a mixture, the "sum of fractions" rule applies; see **12VAC 5-481-3690**. Refer to NRC NUREG-1727 'NMSS Decommissioning Standard Review Plan' for further information on application of the values in this table.

Table 14 was derived using the D and D screening code, Version 1, and its default input parameters. **Table 14** provides criteria which permit licensees to demonstrate compliance with the unrestricted release dose criterion in the license termination rule. The values correspond to screening "derived concentration guidelines" for each specific radionuclide based on the methodology described in NRC NUREG-1727 'NMSS Decommissioning Standard Review Plan'. Sites with building surface contamination levels below those listed in **Table 14** would be deemed acceptable for release for unrestricted use in accordance with the dose criteria in **12VAC5-481-1161**, provided that residual radioactivity has been reduced to ALARA levels. The table is intended for use as criteria to facilitate license termination for many simple routine decommissioning cases without a site-specific dose assessment. For facilities with contamination levels above those in **Table 14**, additional site-specific dose assessments may be necessary, and licensees should refer to NRC NUREG-1727 'NMSS Decommissioning Standard Review Plan' regarding acceptable methods for conducting the appropriate dose assessment.

References: The D and D code can be installed by downloading the self-extracting program file, setup.exe, accessed through the web site: <http://techconf.llnl.gov/radcri/java.html>. NUREG-1727 '*NMSS Decommissioning Standard Review Plan*', NRC NUREG - 1549, 'Decision Methods for Dose Assessment to Comply With Radiological Criteria for License Termination,' dated July 1998, and NRC NUREG/CR - 5512, Vol. #3, 'Residual Radioactive Contamination From Decommissioning, Parameter Analysis,' dated April 25, 1996, can also be accessed through NRC's web site at www.nrc.gov.

Survey Record Requirements

Each survey record should include the following:

- A diagram of the area surveyed (See **Figure 1**);
- A list of items and equipment surveyed;
- Specific locations on the survey diagram where wipe test was taken;
- Ambient radiation levels with appropriate units;
- Contamination levels with appropriate units;
- Make and model number of instruments used;
- Background levels; and
- Name of the person making the evaluation and recording the results and date.

Licensees should record contamination levels observed and procedures followed for incidents involving contamination of individuals. The record should include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor's signature.

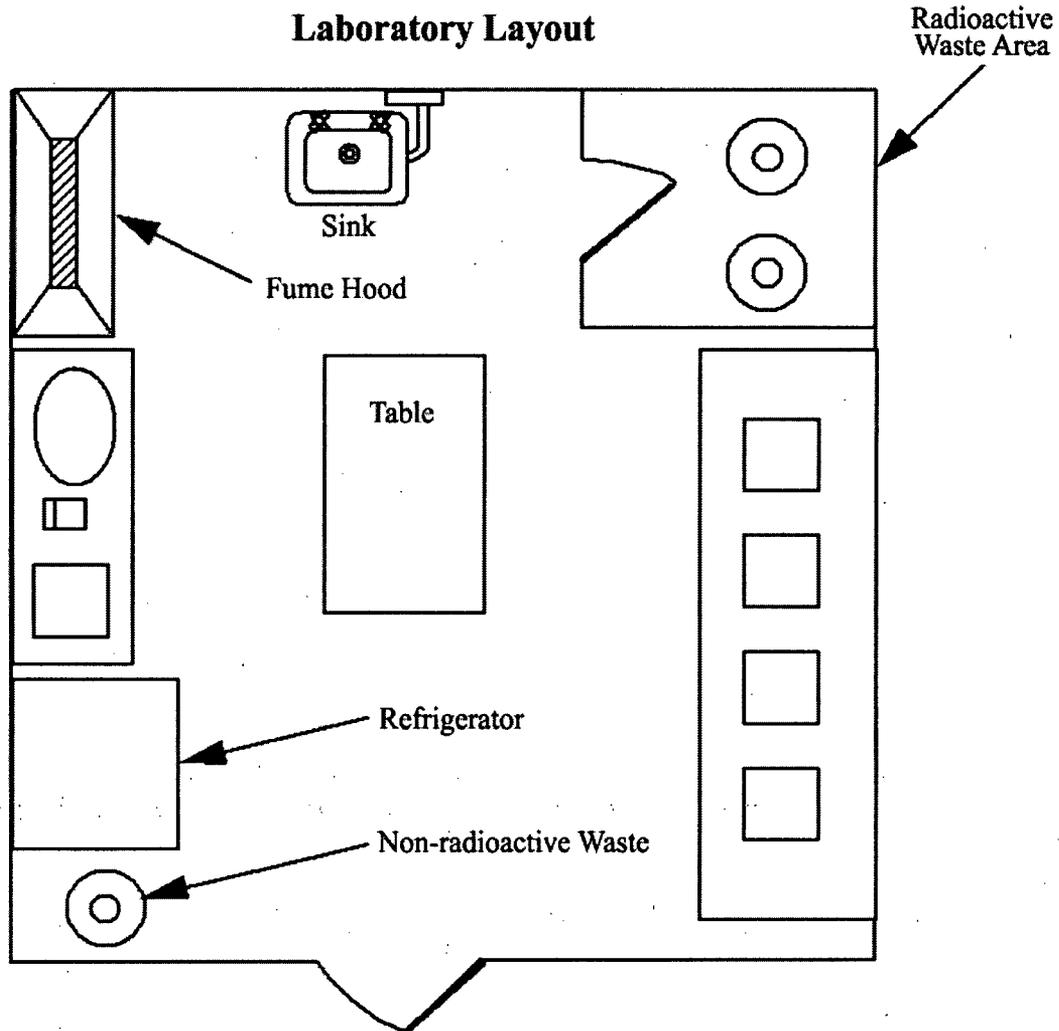


Figure 1: Laboratory Layout. This is an example of a laboratory survey map

Air Monitoring in the Workplace

Air sampling can be used to do the following:

- Determine whether the confinement of radioactive materials is effective;
- Measure airborne radioactive material concentrations in the workplace;
- Estimate worker intakes of radioactive material;
- Determine posting requirements;
- Determine what protective equipment and measures are appropriate; and
- Warn of significantly elevated levels of airborne radioactive materials.

If bioassay measurements are used to determine worker doses of record, air sampling may be used to determine time of intake and to determine which workers should have bioassay measurements. The use of engineering controls and a good air sampling program may eliminate need for bioassays.

Refer to NRC Regulatory Guide 8.25, Revision 1, '*Air Sampling in the Workplace*' dated June 1992 and NRC NUREG - 1400, '*Air Sampling in the Workplace*' dated September 1993 for further guidance on the air sampling.

Airborne Effluent Release Monitoring

When practicable, airborne radioactive effluents should be released from monitored release points (e.g., monitored stacks, discharges, vents) to provide accurate measurements to estimate public exposure. Licensees should verify the performance of effluent monitoring systems by regular calibration (at least annually) to ensure their reliability.

NRC Regulatory Guide 4.20, '*Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors*' dated December 1996, provides guidance on methods acceptable (calculation or COMPLY code) to the agency for compliance with the constraint on air emissions to the environment.

NRC Regulatory Guide 8.37, '*ALARA Levels for Effluents from Materials Facilities*,' dated July 1993, provides guidance on designing an acceptable program for establishing and maintaining ALARA levels for gaseous and liquid effluents at materials facilities.

For release points for which monitoring is not practicable, the licensee should estimate the magnitude of the unmonitored effluents. These unmonitored releases will occur anytime unsealed material is handled outside a fume hood or other device that will control the releases. The licensee should include these estimates when demonstrating compliance with dose limits and ALARA goals. Unmonitored releases may be estimated based on the quantity of material used in these areas or the number of procedures performed or other appropriate methods. The unmonitored effluents should not exceed 30% of the total estimated effluent releases or 10% of the permissible air effluent in **12VAC5-481-3690**, whichever is greater.

Effluent monitoring systems should be designed in accordance with ANSI N13.1 (1969), '*Document to Sampling Airborne Radioactive Materials in Nuclear Facilities*' and ANSI N42.18, '*Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents*.'

Liquid Effluent Release Monitoring

The licensee should evaluate the concentrations of radioactive material in water that is released to the environment and to the sanitary sewer. The licensee must show that these releases meet the limits in **12VAC5-481-720** and **12VAC5-481-930**, respectively.

The topic of sanitary sewerage releases is more fully discussed in **Appendix T**.

Bioassay Monitoring

Frequency of Required Bioassay Measurements

Determining the appropriate frequency of routine bioassay measurements depends upon the exposure potential and the physical and chemical characteristics of the radioactive material and the route of entry to the body. Consider the following elements:

- Potential exposure of the individual;

- Retention and excretion characteristics of the radionuclides;
- Sensitivity of the measurement technique; and
- Acceptable uncertainty in the estimate of intake and committed dose equivalent.

Bioassay measurements used for demonstrating compliance with the occupational dose limits should be conducted often enough to identify and quantify potential exposures and resultant intakes that, during any year, are likely to collectively exceed 0.1 times the ALI. The 10% ALI criterion is consistent with **12VAC5-481-760**, which requires licensees to monitor intakes and assess occupational doses for exposed individuals who are likely to exceed 10% of the applicable limit (i.e., intakes likely to exceed 0.1 ALI for adults).

Separate categories of bioassay measurements, routine measurements and special measurements further determine the frequency and scope of measurements.

Routine Measurements

Routine measurements include baseline measurements, periodic measurements, and termination measurements. These measurements should be conducted to confirm that appropriate controls exist and to assess dose. The method of bioassay selected (for example, whole body counting, urinalysis, etc) and the samples collected will vary according to the radionuclide and the compound to which it is attached. Sample collection procedures should be developed to ensure that appropriate types, sizes, and numbers of samples are collected that will provide appropriate physiological information for the dose assessment.

An individual's baseline measurement of radioactive material within the body should be conducted before beginning work that involves exposure to radiation or radioactive materials for which monitoring is required.

In addition to the baseline measurements, periodic bioassay measurements should be performed. The frequency of periodic measurements should be based on the likelihood of significant exposure of the individual. In determining the worker's likely exposure, consider such information as the worker's access, work practices, measured levels of airborne radioactive material, and exposure time. Periodic measurements should be made when the cumulative exposure to airborne radioactivity, since the most recent bioassay measurement, is > 0.02 ALI (40 DAC hours). Noble gases and airborne particulates with a radioactive half-life of less than 2 hours should be excluded from the evaluation, since external exposure generally controls these radionuclides.

At a minimum, periodic measurements should be conducted annually. Periodic measurements provide additional information on any long-term accumulation and retention of radioactive material in the body, especially for exposures to concentrations of airborne radioactive material below monitoring thresholds.

When an individual is no longer subject to the bioassay program, because of change in employment status, termination bioassay measurement should be made, when practicable, to ensure that any unknown intakes are quantified.

Special Monitoring

Because of uncertainty in the time of intakes and the absence of other data related to the exposure (e.g., physical and chemical forms, exposure duration), correlating positive results to actual intakes for routine measurements can sometimes be difficult. Abnormal and inadvertent intakes from situations such as a failed respiratory protective device, inadequate engineering controls, inadvertent ingestion, contamination of a wound, or skin absorption, should be evaluated on a case-by-case basis. When determining whether potential intakes should be evaluated, consider the following circumstances:

- The presence of unusually high levels of facial and/or nasal contamination;
- Entry into airborne radioactivity areas without appropriate exposure controls;
- Operational events with a reasonable likelihood that a worker was exposed to unknown quantities of airborne radioactive material (e.g., loss of system or container integrity);
- Known or suspected incidents of a worker ingesting radioactive material;
- Incidents that result in contamination of wounds or other skin absorption; and
- Evidence of damage to or failure of a respiratory protective device.

References: Can be accessed through the NRC's web site at www.nrc.gov and ANSI's web site at www.ansi.org.

- NUREG-1727 '*NMSS Decommissioning Standard Review Plan*'
- Federal Register Notice, '*Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination*,' Volume 63, Number 222, Page 64132, dated November 18, 1998
- NRC Regulatory Guide 4.20, '*Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors*,' dated December 1996
- NRC Regulatory Guide 8.9, Revision 1, '*Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program*,' dated July 1993
- NRC Regulatory Guide 8.23, Revision 1, '*Radiation Safety Surveys at Medical Institutions*,' dated January 1981
- NRC Regulatory Guide 8.25, Revision 1, '*Air Sampling in the Workplace*,' dated June 1992
- NRC Regulatory Guide 8.32, '*Criteria for Establishing a Tritium Bioassay Program*,' dated July 1988
- NRC Regulatory Guide 8.37, '*ALARA Levels for Effluents from Materials Facilities*,' dated July 1993
- NUREG - 1400, '*Air Sampling in the Workplace*,' dated September 1993
- NUREG - 1549, '*Decision Methods for Dose Assessment to Comply With Radiological Criteria for License Termination*,' dated July 1998
- NUREG/CR - 5512, Vol. #3, '*Residual Radioactive Contamination From Decommissioning, Parameter Analysis*,' dated April 25, 1996
- NUREG/CR - 4884, '*Interpretation of Bioassay Measurements*,' dated July 1987
- Additional References
- ANSI N13.1 (1969), '*Document to Sampling Airborne Radioactive Materials in Nuclear Facilities*,' dated 1991
- ANSI N42.18, '*Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents*,' 1991
- NCRP Commentary No. 3, '*Screening Techniques for Determining Compliance with Environmental Standards*,' published in January 1989 and the addendum published in October 1989

Appendix R

Leak Test Procedures

Leak Test Procedures

This appendix provides applicants and licensees with leak test procedures and sample calculations for determining activity on a wipe test sample.

Frequency for Conducting Leak Tests of Sealed Sources

Leak tests will be conducted at 6 month intervals or as specified in the respective SSD Registration Certificate.

Procedure for Performing Leak Testing and Analysis

For each source to be tested, list identifying information such as manufacturer, model number, serial number, radionuclides, and activity.

- If available, use a survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area (but not directly from the surface of a source) where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 185 becquerels (0.005 microcurie) of the radionuclides and ensure that its calibration is current.
- Using the selected instrument, count and record background count rate.
- Calculate efficiency.

For example:
$$\frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of std in Bq}} = \text{efficiency in cpm/Bq}$$

Where: cpm = counts per minute
 std = standard
 bkg = background
 Bq = becquerel

- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in becquerels (or microcuries).

For example:
$$\frac{[(\text{cpm from wipe sample}) - (\text{cpm from bkg})]}{\text{efficiency in cpm/Bq}} = \text{Bq on wipe sample}$$

- Sign and date the list of sources, data and calculations. Retain records for 5 years (12VAC5-481-1010).
- If the wipe test activity is 185 Bq (0.005 Ci) or greater, notify the RSO, so that the source can be withdrawn from use, disposed of properly, and VDH notified in writing within 5 days.

Appendix S

Transportation

Transportation

Part 1: Major DOT Regulations

The major areas in the DOT regulations that are most relevant for transportation of licensed material shipped as Type A quantities are as follows:

- Hazardous Materials Table: **49 CFR 172.101, App. A, Subpart B**, list of hazardous substances and reportable quantities (RQ), Table 2: Radionuclides
- Shipping Papers: **49 CFR 172.200-204**: General entries, description, additional description requirements, shipper's certification
- Package Markings: **49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324**: General marking requirements for non-bulk packagings, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging
- Package Labeling: **49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440**: General labeling requirements, prohibited labeling, radioactive materials, placement of labels, specifications for radioactive labels
- Placarding of Vehicles: **49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.510; 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556**: Applicability, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, specifications for RADIOACTIVE placards
- Emergency Response Information: **Subpart G, 49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604**: Applicability and general requirements, emergency response information, emergency response telephone number
- Training: **Subpart H, 49 CFR 172.702, 49 CFR 172.704**: Applicability and responsibility for training and testing, training requirements
- Shippers - General Requirements for Shipments and Packaging: **Subpart I, 49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.412, 49 CFR 173.415, 49 CFR 173.431, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.443, 49 CFR 173.448, 49 CFR 173.475, 49 CFR 173.476**: Definitions, general design requirements, additional design requirements for Type A packages, authorized Type A packages, activity limits for Type A packages, requirements for determining A₁ and A₂, table of A₁ and A₂ values for radionuclides, radiation level limitations, contamination control, general transportation requirements, quality control requirements prior to each shipment, approval of special form radioactive materials
- Radiation Protection Program for Shippers and Carriers: **Subpart I, 49 CFR 172.800, 49 CFR 172.802, 49 CFR 172.804**: Applicability of the radiation protection program, radiation protection program, record keeping, and notifications
- Carriage by Public Highway - General Information and Regulations: **Subpart A, 49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842**: Driver training, shipping paper, general requirements (secured against movement), Class 7 (radioactive) material.

Part 2: Sample Shipping Documents, Placards and Labels

Hazard Communications for Class 7 (Radioactive) Materials		
DOT Shipping Papers (49 CFR 172.200-205)		
NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials		
Entries Always Required Unless Excepted	Additional Entries Sometimes Required	Optional Entries
<ul style="list-style-type: none"> The basic description, in sequence: Proper Shipping Name, Hazard Class (7), U.N. Identification Number 24 hour emergency response telephone number Name of shipper Proper page numbering (Page 1 of 4) Except for empty and bulk packages, the total quantity (mass, or volume for liquid), in appropriate units (lbs, mL....) If not special form, chemical and physical form The name of each Radionuclides (95% rule) and total package activity. The activity must be in SI units (e.g., Bq, TBq), or both SI units and customary units (e.g., Ci, mCi). However, for <u>domestic shipments</u>, the activity may be expressed in terms of customary units only, until 4/1/97. For each labeled package: <ul style="list-style-type: none"> The category of label used; The transport index of each package with a Yellow-II or Yellow-III label Shipper's certification (not required of private carriers) 	<p><u>Materials-Based Requirements:</u></p> <ul style="list-style-type: none"> If hazardous substance, "RQ" as part of the basic description The LSA or SCO group (e.g., LSA-II) "Highway Route Controlled Quantity" as part of the basic description, if HRCQ Fissile material information (e.g., "Fissile Exempt," controlled shipment statement [see §172.203(d)(7)]) If the material is considered hazardous waste and the word waste does not appear in the shipping name, then "waste" must precede the shipping name (e.g., Waste Radioactive Material, nos, UN2982) "Radioactive Material" if not in proper shipping name <p><u>Package-Based Requirements:</u></p> <ul style="list-style-type: none"> Package identification for DOT Type B or NRC certified packages IAEA CoC ID number for export shipments or shipments using foreign-made packaging (see §173.473) <p><u>Administrative-Based Requirements:</u></p> <ul style="list-style-type: none"> "Exclusive Use-Shipment" Instructions for maintenance of exclusive use-shipment controls for LSA/SCO strong-light or NRC certified LSA (§ 173.427) If a DOT exemption is being used, "DOT-E" followed by the exemption number 	<ul style="list-style-type: none"> The type of packaging (e.g., Type A, Type B, IP-1,) The Technical/chemical name may be included (if listed in §172.203(k), in parentheses between the proper shipping name and hazard class; otherwise inserted in parenthesis after the basic description) Other information is permitted (e.g., functional description of the product), provided it does not confuse or detract from the proper shipping name or other required information For fissile radionuclides, except Pu-238, Pu-239, and Pu-241, the weight in grams or kilograms may be used <i>in place of</i> activity units. For Pu-238, Pu-239, and Pu-241, the weight in grams or kilograms may optionally be entered <i>in addition to</i> activity units [see § 172.203(d)(4)] Emergency response hazards and guidance information (§§ 172.600-604) may be entered on the shipping papers, or may be carried with the shipping papers [§ 172.602(b)]
Some Special Considerations/Exceptions for Shipping Paper Requirements		
<ul style="list-style-type: none"> Shipments of Radioactive Material, excepted packages, under UN2910 (e.g., Limited Quantity, Empty packages, and Radioactive Instrument and Article), are excepted from shipping papers. For limited quantities (§173.421), this is only true if the limited quantity is not a hazardous substance (RQ) or hazardous waste (40 CFR 262) Shipping papers must be in the pocket on the left door, or readily visible to person entering driver's compartment and within arm's reach of the driver For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, be designated by an "X" (or "RQ") in the hazardous material column, or be highlighted in a contrasting color 		

Hazard Communications for Class 7 (Radioactive) Materials

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 A₂ quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52. Also, for bulk packages of these materials, the orange panel marking with the UN identification number is not required.
- Placards are required any vehicle containing package with a Highway Route Controlled Quantity (HRCQ). In this case, the placard must be placed in a square background as shown below (see §173.507(a))

Radioactive Placard

<p>Size Specs:</p> <p>Sides: ≥ 273 mm (10.8 in.)</p> <p><i>Solid line Inner border:</i> About 12.7 mm (0.5 in.) from edges</p> <p>Lettering: ≥ 41 mm (1.6 in.)</p> <p><i>Square for HRCQ:</i> 387mm (15.25 in.) outside length by 25.4 mm (1 in.) thick</p>	 <p>49 CFR 172.556</p> <p>RADIOACTIVE PLACARD (Domestic)</p> <p><i>Base of yellow solid area:</i> 29 ± 5 mm (1.1 ± 0.2 in.) above horizontal centerline</p>	 <p>IAEA SS 6 (1985) paras. 443-444</p> <p>RADIOACTIVE PLACARD (International)</p>	 <p>See 49 CFR 172.527 AND 556</p> <p>RADIOACTIVE PLACARD FOR HIGHWAY ROUTE CONTROLLED QUANTITY (either domestic or international placard could be in middle)</p>
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Some Special Considerations/Exceptions for Placarding Requirements

- Domestically, substitution of the UN ID number for the word "RADIOACTIVE" on the placard is prohibited for Class-7 materials. However, some import shipments may have this substitution in accordance with international regulations.
- Bulk packages require the orange, rectangular panel marking containing the UN ID number, which must be placed adjacent to the placard (see §172.332) [NOTE: except for LSA/ SCO exclusive use under §173.427, as above]
- If placarding for more than one hazard class, subsidiary placards must not display the hazard class number. Uranium Hexafluoride (UF₆) shipments ≥ 454 kg (1001 lbs) require both RADIOACTIVE and CORROSIVE (Class 8) placarding
- For shipments of radiography cameras in convenience overpacks, if the overpack does not require a RADIOACTIVE - YELLOW III label, vehicle placarding is not required (regardless of the label which must be placed on the camera)

Hazard Communications for Class 7 (Radioactive) Materials

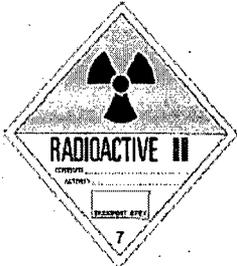
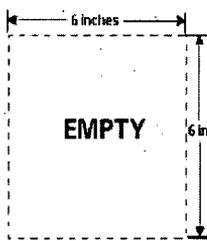
Labeling Packages (49 CFR 172.400-450)

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

<p>Size: Sides: ≥ 100 mm (3.9 in.)</p> <p>Border: 5-6.3 mm (0.2-0.25 in.)</p>				
	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:	Tl = 0 [1 meter dose rate < 0.0005 mSv/hr (0.05 mrem/hr)]	Tl ≤ 1 [1 meter dose rate < 0.01 mSv/hr (1 mrem/hr)]	Tl ≤ 10 [1 meter dose rate < 0.1 mSv/hr (10 mrem/hr)] [Note: There is no package Tl limit for exclusive-use]	
Notes:	<ul style="list-style-type: none"> Any package containing a Highway Route Controlled Quantity (HRCQ) must bear YELLOW-III label Although radiation level transport indices (TIs) are shown above, for fissile material, the TI is typically determined on the basis of criticality control 			

Content on Radioactive Labels

- RADIOACTIVE Label must contain (entered using a durable, weather-resistant means):
 - The radionuclides in the package (with consideration of available space). Symbols (e.g., Co-60) are acceptable
 - The activity in SI units (e.g., Bq, TBq), or both SI units with customary units (e.g., Ci, mCi) in parenthesis. However, for domestic shipments, the activity may be expressed in terms of customary units only, until 4/1/97.
 - The Transport Index (TI) in the supplied box. The TI is entered only on YELLOW-II and YELLOW-III labels

Some Special Considerations/Exceptions for Labeling Requirements

- For materials meeting the definition of another hazard class, labels for each secondary hazard class need to be affixed to the package. The subsidiary label may not be required on opposite sides, and must not display the hazard class number
- Radioactive Material, excepted packages, under UN2910 (e.g., Limited Quantity, Empty packages, and Radioactive Instrument and Article), are excepted from labeling. However, if the excepted quantity meets the definition for another hazard class, it is re-classed for that hazard. Hazard communication requirements for the other class are required
- Labeling exceptions exist for shipment of LSA or SCO required by § 173.427 to be consigned as exclusive use
- The "Cargo Aircraft Only" label is typically required for radioactive materials packages shipped by air (§ 172.402(c))

Package and Vehicle Contamination Limits (49 CFR 173.443) This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials		
NOTE: All values for contamination in DOT rules are to be averaged over each 300 cm ² Sufficient measurements must be taken in the appropriate locations to yield representative assessments &(means the sum of beta emitters, gamma emitters, and low-toxicity alpha emitters " means the sum of all other alpha emitters (i.e., other than low-toxicity alpha emitters)		
The Basic Contamination Limits for All Packages: 49 CFR 173.443(a), Table 11	General Requirement: Non-fixed (removable) contamination must be kept as low as reasonably achievable (ALARA)	
	&(0.4 Bq/cm² = 40 Bq/100 cm² = 1x10⁻⁶ Ci/cm² = 2200 dpm/100 cm²	
	" 0.04 Bq/cm² = 4 Bq/100 cm² = 1x10⁻⁶ Ci/cm² = 220 dpm/100 cm²	
The following exceptions and deviations from the above basic limits exist:		
Deviation from Basic Limits	Regulation 49 CFR §§	Applicable Location and Conditions Which must Be Met:
10 times the basic limits	173.443(b) and 173.443(c) Also see 177.843 (highway)	On any external surface of a package in an exclusive use shipment, during transport including end of transport. Conditions include: (1) Contamination levels at beginning of transport must be below the basic limits. (2) Vehicle must not be returned to service until radiation level is shown to be ≤ 0.005 mSv/hr (0.5 mrem/hr) at any accessible surface, and there is no significant removable (non-fixed) contamination.
10 times the basic limits	173.443(d) Also see 177.843 (highway)	On any external surface of a package, at the beginning or end of transport, if a closed transport vehicle is used, solely for transporting radioactive materials packages. Conditions include: (1) A survey of the interior surfaces of the empty vehicle must show that the radiation level at any point does not exceed 0.1 mSv/hr (10 mrem/hr) at the surface, or 0.02 mSv/hr (2 mrem/hr) at 1 meter (3.3 ft). (2) Exterior of vehicle must be conspicuously stenciled, "For Radioactive Materials Use Only" in letters at least 76 mm (3 inches) high, on both sides. (3) Vehicle must be kept closed except when loading and unloading.
100 times the basic limits	173.428	Internal contamination limit for excepted package-empty packaging , Class 7 (Radioactive) Material, shipped in accordance with 49 CFR 173.428. Conditions include: (1) The basic contamination limits (above) apply to external surfaces of package. (2) Radiation level must be ≤ 0.005 mSv/hr (0.5 mrem/hr) at any external surface. (3) Notice in §173.422(a)(4) must accompany shipment. (4) Package is in unimpaired condition & securely closed to prevent leakage. (5) Labels are removed, obliterated, or covered, and the "empty" label (§172.450) is affixed to the package.
In addition, after any incident involving spillage, breakage, or suspected contamination, the modal-specific DOT regulations (§177.861(a), highway; §174.750(a), railway; and §175.700(b), air) specify that vehicles, buildings, areas, or equipment have "no significant removable surface contamination," before being returned to service or routinely occupied. The carrier must also notify offer or at the earliest practicable moment after incident.		

Minimum Required Packaging For Class 7 (Radioactive) Materials							
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials							
Quantity:	< 70 Bq/g (< 0.002 Ci/g)	Limited Quantity	(\$173.421)	A ₁ /A ₂ value	(\$173.435)	1 rem/hr at 3 m, unshielded	(\$173.427)
Non-LSA/SCO:	Excepted	Type A	Type B ³				
Domestic or International LSA/SCO: LSA-I solid, (liquid) ¹ SCO-I	Excepted	IP-I	Type B ³				
LSA-I Liquid LSA-II Solid, (liquid or gas) ¹ (LSA-III) ¹ SCO-II		IP-II	Type B ³				
LSA-II Liquid or Gas LSA-III		IP-III	Type B ³				
Domestic (only) LSA/SCO: LSA-I, II, III; SCO-I, II	Excepted	Strong-tight ²	DOT Spec. 7A Type A	Type B ³ NRC Type A LSA ^{3,4}			

1. For entries in parentheses, exclusive use is required for shipment in an IP (e.g., shipment of LSA-I liquid in an IP-I packaging would require exclusive use consignment)
2. Exclusive use required for strong-tight container shipments made pursuant to §173.427(b)(2)
3. Subject to conditions in Certificate, if NRC package
4. Exclusive use required, see §173.427(b)(4). Use of these packages expires on 4/1/99 (10 CFR 71.52)

Package and Vehicle Radiation Level Limits (49 CFR 173.441) ^A				
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials				
Transport Vehicle Use:	Non-Exclusive	Exclusive		
Transport Vehicle Type:	Open or Closed	Open (flat-bed)	Open w/Enclosure ^B	Closed
Package (or freight container) Limits:				
External Surface	2 mSv/hr (200 mrem/hr)	2 mSv/hr (200 mrem/hr)	10 mSv/hr (1000 mrem/hr)	10 mSv/hr (1000 mrem/hr)
Transport Index (TI) ^C	10	no limit		
Roadway or Railway Vehicle (or freight container) Limits:				
Any point on the outer surface	N/A	N/A	N/A	2 mSv/hr (200 mrem/hr)
Vertical planes projected from outer edges		2 mSv/hr (200 mrem/hr)	2 mSv/hr (200 mrem/hr)	N/A
Top of...		load: (200 mrem/hr)	enclosure: 2 mSv/hr (200 mrem/hr)	vehicle: 2 mSv/hr (200 mrem/hr)
2 meters from...		vertical planes: 0.1 mSv/hr (10 mrem/hr)	vertical planes: 0.1 mSv/hr (10 mrem/hr)	outer lateral surfaces: 0.1 mSv/hr (10 mrem/hr)
Underside		2 mSv/hr (200 mrem/hr)		
Occupied position	N/A ^D	0.02 mSv/hr (2 mrem/hr) ^E		
Sum of package TI's	50	no limit ^F		

- A. The limits in this table do not apply to excepted packages - see 49 CFR 173.421-426
- B. Securely attached (to vehicle), access-limiting enclosure; package personnel barriers are considered as enclosures
- C. For nonfissile radioactive materials packages, the dimensionless number equivalent to maximum radiation level at 1m (3.3 feet) from the exterior package surface, in millirem/hour
- D. No dose limit is specified, but separation distances apply to Radioactive Yellow-II or Radioactive Yellow-III labeled packages
- E. Does not apply to private carrier wearing dosimetry if under radiation protection program satisfying 10 CFR 20 or 49 CFR 172 Subpart I
- F. Some fissile shipments may have combined conveyance TI limit of 100 - see 10 CFR 71.59 and 49 CFR 173.457

Hazard Communications for Class 7 (Radioactive) Materials

Marking Packages (49 CFR 172.300-338)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments. This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials.

Markings Always Required Unless Excepted	Additional Markings Sometimes Required	Optional Markings
<p><u>Non-Bulk Packages</u></p> <ul style="list-style-type: none"> • Proper shipping name • U.N. identification number • Name and address of consignor or consignee, <i>unless</i>: <ul style="list-style-type: none"> - highway only and no motor carrier transfers, <u>or</u> - part of carload or truckload lot or freight container load, and entire contents of railcar, truck, or freight container are shipped from one consignor to one consignee [see §172.301(d)] <hr style="border-top: 1px dashed black;"/> <p><u>Bulk Packages</u> (i.e., net capacity greater than 119 gallons as a receptacle for liquid, or 119 gallons and 882 pounds as a receptacle for solid, or water capacity greater than 1000 lbs, with no consideration of intermediate forms of containment)</p> <ul style="list-style-type: none"> • U.N. identification number, on orange, rectangular panel (see §172.332) - some exceptions exist 	<p><u>Materials-Based Requirements:</u></p> <ul style="list-style-type: none"> • If in excess of 110 lbs (50 kg), Gross Weight • If non-bulk <u>liquid</u> package, underlined double arrows indicating upright orientation (two opposite sides) [ISO Std 780-1985 marking]  • If a Hazardous substance in non-bulk package, the letters "RQ" in association with the proper shipping name <p><u>Package-Based Requirements:</u></p> <ul style="list-style-type: none"> • The package type if Type A or Type B (½" or greater letters) • The specification-required markings [e.g., for Spec. 7A packages: "DOT 7A Type A" and "Radioactive Material" (see §178.350-353)] • For approved packages, the certificate ID number (e.g., USA/9166/B(U), USA/9150/B(U)-85, ...) • If Type B, the trefoil (radiation) symbol per Part 172 App. B [size: outer radius ≥ 20 mm (0.8 in)]  • For NRC certified packages, the model number, gross weight, and package ID number (10 CFR 71.85) <p><u>Administrative-Based Requirements:</u></p> <ul style="list-style-type: none"> • If a DOT exemption is being used, "DOT-E" followed by the exemption number • If an export shipment, "USA" in conjunction with the specification markings or certificate markings 	<ul style="list-style-type: none"> • "IP-1," "IP-2," or "IP-3" on industrial packaging is recommended • Both the name and address of consignor and consignee are recommended • Other markings (e.g., advertising) are permitted, but must be sufficiently away from required markings and labeling

Some Special Considerations/Exceptions for Marking Requirements

- Marking is required to be: (1) durable, (2) printed on a package, label, tag, or sign, (3) unobscured by labels or attachments, (4) isolated from other marks, and (5) be representative of the hazmat contents of the package
- Limited Quantity (§173.421) packages and Articles Containing Natural Uranium and Thorium (§173.426) must bear the marking "radioactive" on the outside of the inner package or the outer package itself, and are excepted from other marking. The excepted packages shipped under UN 2910 must also have the accompanying statement that is required by §173.422.
- Empty (§173.428) and Radioactive Instrument and Article (§173.424) packages are excepted from marking
- Shipment of LSA or SCO required by §173.427 to be consigned as exclusive use are excepted from marking except that the exterior of each nonbulk package must be marked "Radioactive-LSA" or "Radioactive-SCO," as appropriate. Examples of this category are domestic, strong-tight containers with less than an A₂ quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52.
- For bulk packages, marking may be required on more than one side of the package (see 49 CFR 172.302(a))

Example Certificate Enclosed In/on Package, Included with the Packing List or Otherwise Forwarded with the Package)

This package conforms to the conditions, and limitations specified in 49 CFR 173.424 for radioactive material, excepted package-instruments or articles, UN2910.

(Signed) Radiation Safety Officer

Appendix T

Waste Management Procedures

Waste Management Procedures

General Guidelines

- All radioactivity labels must be defaced or removed from containers and packages prior to disposal in ordinary (non-radioactive) waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
- Remind workers that non-radioactive waste such as leftover reagents, boxes, and packaging material should not be mixed with radioactive waste.
- Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
- In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and costs.
- Waste management program should include waste handling procedures for the users within their laboratories or assigned areas, and for waste handlers who may collect waste from areas of use to bring to the storage area for eventual disposal.
- Housekeeping staff should be provided adequate training to avoid the possibility of unauthorized disposal or exposure of these individuals to radioactive materials or to radiation.

Procedure for Disposal by Decay-in-storage (DIS)

- Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.
- Short-lived waste should be segregated from long-lived waste (half-life greater than 120 days) at the source.
- Waste should be stored in suitable well-marked containers, and the containers should provide adequate shielding.
- Liquid and solid wastes must be stored separately.
- When the container is full, it should be sealed. The sealed container should be identified with a label affixed or attached to it.
- The identification label should include the date when the container was sealed, the longest-lived radioisotope in the container, date when ten half-lives of the longest-lived radioisotope will have transpired, and the initials of the individual who sealed the container. The container may be transferred to the DIS area.
- The contents of the container should be allowed to decay for at least 10 half-lives of the longest-lived radioisotope in the container.
- Prior to disposal as ordinary trash, each container should be monitored as follows:
 - Check the radiation detection survey meter for proper operation;
 - Survey the contents of each container in a low background area;
 - Remove any shielding from around the container;
 - Monitor all surfaces of the container;
 - Discard the contents as ordinary trash only if the surveys of the contents indicate no residual radioactivity, i.e., surface readings are indistinguishable from background; and
 - If the surveys indicate residual radioactivity, return the container to DIS area and contact the RSO for further instructions.

- If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste (used or unused material, gloves, etc.), survey instrument used, and the initials of the individual performing surveys and disposing of the waste.

Procedure for Disposal of Liquids Into Sanitary Sewerage

- Confirm that sewerage system is a public system, not a private sewerage system, septic system, or leach field.
- Confirm that the liquid waste being discharged is soluble or biological material that is readily dispersible in water.
- Calculate the amount of each radioisotope that can be discharged by using the information from prior, similar discharges and the information in **12VAC5-481-3690**.
- Make sure that the amount of each radioisotope does not exceed the monthly and annual discharge limits specified in **12VAC5-481-930** and **12VAC5-481-3690**.
- Record the date, radioisotope(s), estimated activity of each radioisotope, location where the material is discharged, and the initials of the individual discharging the waste.
- Liquid waste should be discharged only via designated sinks, toilets or release points.
- Discharge liquid waste slowly with water running from the faucet to dilute it.
- Survey the sink and surrounding work surfaces to confirm that no residual material or contamination remained in the sink or on work surfaces.
- Prior to leaving the area, decontaminate all areas or surfaces, if found to be contaminated.
- Maintain records of each radioisotope and its quantity and concentration that is released into the sanitary sewer system.