
Commonwealth of Virginia Radiation Protection Regulatory Guide



Guidance for 12VAC5-481 Part XII Irradiators

ORH-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 or licensees. VAREGS are not substitutes for **12VAC5-481 ‘Virginia Radiation Protection Regulations’**; therefore, compliance with them is not required. Methods and solutions different from those set forth in this guide will be acceptable if they provide a basis for the Virginia Department of Health (VDH), Radioactive Materials Program, to determine if a radiation protection program meets the current rule and protects health and safety.

Comments and suggestions for improvements in this VAREG are encouraged 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** 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 **12VAC5-490**.

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. If submitted, proprietary information and other sensitive information should be clearly identified and a request made to withhold from public disclosure.
- Submit an original signed application along with attachments (if any). This submission can be made via scanned copies forwarded via facsimile or electronic mail or via postal mail of the documents.
- Submit the application fee (for new licenses only).
- Retain one copy of the 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.

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

LICENSES

Applicants should study this document, related guidance, and all applicable regulations carefully before completing the VDH form, ‘Application for a Radioactive Material License 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**.

SAFETY CULTURE

Nuclear safety culture is defined as the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment. Individuals and organizations performing regulated activities bear the primary responsibility for safely handling and securing these materials. Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal conflict situations (e.g., production versus safety, schedule versus safety, and cost of the effort versus safety). **Table 3** show traits of a positive nuclear safety culture.

Table 3: Traits of a Positive Nuclear Safety Culture

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

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

APPLICABLE RULE

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

The following parts of **12VAC5-481 'Virginia Radiation Protection Regulations'** contain requirements applicable to 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. If submitted, proprietary information and other sensitive information should be clearly identified and a request made to withhold from public disclosure.
- Submit an original, signed application. This submission can be made via scanned copies forwarded via facsimile or electronic mail or via postal mail of the documents.
- Retain one copy of the license application for your future reference.

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

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

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

Item 2: Name and Mailing Address Of Applicant

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

Notify the agency of changes in mailing address.

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

Note: The agency must be notified 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 **written consent prior** to transferring ownership or control of the license, or, as some licensees call it, 'transferring the license'.

Discussion: Transfer of control may be the 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 VDH written consent. This is to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid licenses issued by VDH, 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; and
- 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

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

Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains 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.

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

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), unless the applicant has named a different person as the contact. The agency will contact this individual if there are questions about the application.

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

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).

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: Individual Responsible for the Radiation Safety Program

Item 5.1: Radiation Safety Officer (RSO) Training and Experience

Rule: 12VAC5-481-450, 12VAC5-481-451, 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, 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.

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, 12VAC5-481-451, 12VAC5-481-2260, 12VAC5-481-2270, 12VAC5-481-2280, 12VAC5-481-2680, 12VAC5-481-2730, 12VAC5-481-2760, 12VAC5-481-2830, 12VAC5-481-2840, 12VAC5-481-2850, 12VAC5-481-2860, 12VAC5-481-2880, 12VAC5-481-2900, 12VAC5-481-2910, 12VAC5-481-2930, 12VAC5-481-2940

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, 12VAC5-481-451, 12VAC5-481-630, 12VAC5-481-2270, 12VAC5-481-2680, 12VAC5-481-2830, 12VAC5-481-2930, 12VAC5-481-2940

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, 12VAC5-481-451, 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.

Note: Alternative responses will be evaluated using the criteria listed above.

Reference: NUREG-1345, "Review of Events at Large Pool-Type Irradiators".

Item 7: Radioactive Material

Item 7.1: Sealed Sources and Devices

Rule: **12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-451, 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, 12VAC5-481-2840, 12VAC5-481-2870, 12VAC5-481-2930, 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**.

A maximum possession limit, per isotope, is required to be requested; this should reflect the total number of sealed sources and devices containing a particular isotope (i.e., Cesium-137) that would ever be possessed at any one time, including inactive sources being held for storage and devices awaiting shipment. This should also include sources and devices expected to be purchased at in the future. This limit is isotope specific (i.e., one limit for Cesium-137 and another for Cobalt-60) and not allowed to be exceeded; that is, the total of all sources and devices in the licensee's possession cannot exceed this limit. An amendment request must be made and an amended license received prior to obtaining more sources and devices.

Possession limits can be obtained from information provided by the manufacturer; specifically, the activity provided by the manufacturer on the sources and devices the licensee anticipates acquiring. This information will list each isotope with the activity for the source and device. A simple calculation can be performed with this information by totaling the number of each source and device, per isotope, that the licensee expects to possess at any one time. Licensees are also required to maintain a limit per device. This is separate from the maximum possession limit; this limit is applied to each source and device itself and is typically determined by the manufacturer's Sealed Source and Device Registration Certificate.

NRC or another Agreement State performs a safety evaluation of irradiators before authorizing a manufacturer to distribute the irradiators to specific licensees. The safety evaluation is documented in a Sealed Source and Device Registration (SSDR) Certificate, also called an SSDR Sheet.

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 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.

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 Financial Assurance and Record Keeping for Decommissioning

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

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

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

The requirements for financial assurance are specific to the types and quantities of 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.

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, 12VAC5-481-451, 12VAC5-481-590, 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.

Item 8.2: Access Control

Rule: 12VAC5-481-450, 12VAC5-481-451, 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.

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 mrem) 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).

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.”

Item 8.5: Radiation Monitors

Rule: 12VAC5-481-450, 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.

Item 8.6: Irradiator Pools

Rule: 12VAC5-481-450, 12VAC5-481-2730, 12VAC5-481-2780, 12VAC5-481-2790, 12VAC5-481-2810, 12VAC5-481-2820, 12VAC5-481-2890

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.”

Item 8.7: Source Rack

Rule: **12VAC5-481-450, 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 conveyor systems, the licensee must observe and test the operation 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.

See **Appendix J**, “Construction Monitoring and Acceptance Testing.”

Item 8.8: Power Failures

Rule: 12VAC5-481-450, 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.”

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, 12VAC5-481-2680, 12VAC5-481-2930

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 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.

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 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.

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 4**.

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 4: 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

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, 12VAC5-481-451, 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 which should include conducting physical inventories at intervals not to exceed 6 months to account for all sealed sources, and

- 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.**

Maintain inventory records that 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;
- Date of the inventory;
- Name of individual performing the inventory; and
- For materials transferred or disposed of, the date of the transfer or disposal, name and license number of the recipient, description of the affected radioactive material (e.g., radionuclide, activity, manufacturer’s (or distributor’s) name and model number, serial number).

‘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)

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: Applicants must do either of the following:

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

OR

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

Table 5: Occupational Dose Limits For Adults

Occupational Dose Limits for Adults (12VAC5-481-640)	
<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	

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.

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, 12VAC5-481-2730, 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 6: 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.

Item 9.6: Operating and Emergency Procedures

Item 9.6.1: Operating Procedures

Rule: 12VAC5-481-450, 12VAC5-481-451, 12VAC5-481-490, 12VAC5-481-630, 12VAC5-481-720, 12VAC5-481-840, 12VAC5-481-1151, 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: 12VAC5-481-451, 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**).

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," or IN 83-09: "Safety and Security of Irradiators,".

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.

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,".

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.

Item 9.9: Transportation

Rule: 12VAC5-481-100, 12VAC5-481-451, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-2930, 12VAC5-481-2970, 12VAC5-481-2980, 12VAC5-481-3000, 12VAC5-481-3130, 12VAC5-481-3080, 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.

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, 12VAC5-481-451, 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**.

The licensee should establish and include waste disposal procedures in its radiation safety program.

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, 12VAC5-481-451, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-1161

Criteria: The licensee must do the following:

- Notify the agency, in writing, within 60 days of:
 - The expiration of its license;
 - A decision to permanently cease licensed activity at the entire site or in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to VDH requirements;
 - No principal activities have been conducted at the entire site under the license for a period of 24 months;
 - No principal activities have been conducted for a period of 24 months in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to VDH requirements.
- Submit a decommissioning plan, if required by **12VAC5-481-510**;
- Decommissioning, as required by **12VAC5-481-510 & 12VAC5-481-1161**;
- Submit to the agency, a completed VDH form ‘Certificate of Disposition of Materials’ (**Appendix B**) and demonstrate that the premises are suitable for release for unrestricted use (e.g. results of final survey); and
- Before a license is terminated, send the records important to decommissioning to the agency as required by **12VAC5-481-571**. If licensed activities are transferred or assigned in accordance with **12VAC5-481-500**, transfer records important to decommissioning to the new licensee.

Discussion: For guidance on the disposition of licensed material, see the Item 10.1 Sealed Source Disposal and Transfer. For guidance on decommissioning records, see Item 7.2 Financial Assurance and Record Keeping for Decommissioning.

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

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.

Item 11: License Fees

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. For a listing of application fees, please see **12VAC5-490**. 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.

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**’ (**Appendix A**). **Representatives signing an application must be authorized to make binding commitments and sign official documents on behalf of the applicant.** The agency will return all unsigned applications for proper signature.

Note:

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

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.

Appendix A

VDH Form, ‘Application for a Radioactive Material License Authorizing the Use of 12VAC5-481 Part XII Irradiators’



APPLICATION FOR A NEW 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. 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 box)

New License

CONTACT INFORMATION

Item 2 Name And Mailing Address Of Applicant:

Item 3 Person To Contact Regarding Application:

Applicant’s Telephone Number (Include area code):

() - x

Contact’s Telephone Number (Include area code):

() - x

LOCATION OF RADIOACTIVE MATERIAL

Item 4 Address(es) Where 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)

ELEMENT AND MASS NUMBER	IRRADIATOR MANUFACTURER AND MODEL NUMBER
MAXIMUM QUANTITY	MAXIMUM AMOUNT OF DEPLETED URANIUM (KG)

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

- 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 **12VAC5-490**.)

Application fee enclosed:

Yes 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



APPLICATION FOR RENEWAL OF A NEW 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 renewing a radioactive material license. Failure to provide any information may result in denial or delay.

Instructions – Complete all items. 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 box)

Renewal License Number _____

CONTACT INFORMATION

as listed on current license
OR

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):

as listed on current license

OR

as listed on current license and please add the listed additional locations

OR

see provided information for current information

Address

Telephone Number (Include area code)

() - X

RADIATION SAFETY OFFICER

Item 5. Radiation Safety Officer (RSO) (Check one box and attach evidence of training and experience)

as listed on current license

OR

see attached for proposed Radiation Safety Officer

Name: _____

Telephone Number (Include area code): () - X _____

IRRADIATOR OPERATORS AND INDIVIDUALS WHO REQUIRE UNESCORTED ACCESS

Item 6 Irradiator Operators (Check all that apply)

- As listed on current license
- OR
- 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)

- Correct as listed on license
- OR
- Correct as listed on license and see below for additional
- OR
- See below for all requested material

ELEMENT AND MASS NUMBER	IRRADIATOR MANUFACTURER AND MODEL NUMBER
MAXIMUM QUANTITY	MAXIMUM AMOUNT OF DEPLETED URANIUM (KG)

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

- 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 analysis will be performed at intervals not to exceed 6 months and will be analyzed 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**.

LICENSE FEE

Item 11 License Fees (INTIAL APPLICATION ONLY)

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

Attachment A

Pool Irradiator Applicant's Checklist

Yes	No	Item	Material Needed
		Application	Used the correct form (New for new licensees or Renewal for renewing licensees)
		Application	Checked at least one box and filled in all the required information, as needed, for all Items
		Item 5	Attached training information, as needed, AND attached a description of the organizational structure as required by 12VAC5-481-2680
		Item 6	Attached training information, as needed
		Item 7	Attached financial assurance documentation, as needed
		Item 8.1	Attached facility diagram AND, if needed, alternate information
		Item 8.2	Attached required information and descriptions on access controls
		Item 8.3	Attached required information on shielding
		Item 8.5	Attached required information on radiation monitors
		Item 8.6	If needed, attached required information on the pool liner
		Item 8.7	Attached procedures for source rack protection and associated diagrams
		Item 8.8	Attached loss of power procedures
		Item 9.2	Checked box(es) or attached alternate procedure
		Item 9.3	Attached material receipt and accountability procedure
		Item 9.6	Attached operating and emergency procedures
		Item 9.7	Checked box(es) or attached alternate procedure, including the instrumentation to be used for analysis for dry source storage irradiator OR included a description, as needed, for the pool irradiator
		Item 9.8	Checked box or attached alternate procedure

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:

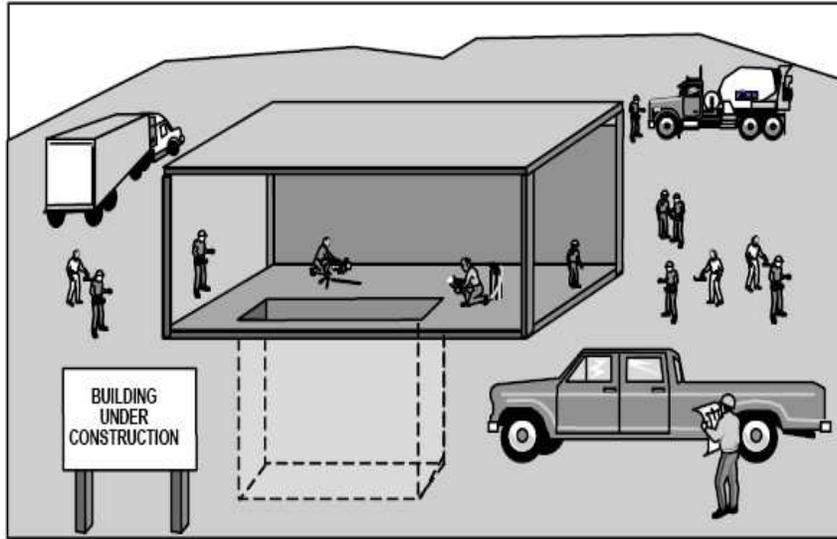
- Describe which non-routine operations will be performed. The principal reason for obtaining this information is to assist in the evaluation of the qualifications of individuals who will conduct the work and the radiation safety procedures they will follow.
- Identify who will perform non-routine operations 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. Before loading sealed sources, irradiator licensees must ensure that the as-built irradiator meets design criteria. **Figure 1** illustrates this point and **Table 7** correlates the components to be checked and the types of tests with the type of irradiator to which the requirement applies.



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Figure 1: Construction Monitoring and Acceptance Testing.

Table 7: 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?
7. Has a National Source Tracking Transaction Report been completed and submitted if required by **12VAC5-481-1151**?
8. Has a security program been implemented to control access to radioactive materials of concern and to protect sensitive security related information required by **12VAC5-481-451**?

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 CaF₂ 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.

Licensees 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, licensees make only those calculations that are needed to demonstrate compliance. The results of these calculations typically result in higher radiation levels than would exist at typical facilities, but 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 8 summarizes the information Leslie has on the irradiator.

Table 8: 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 9** below.

Table 9: 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 5 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 10: 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 11: 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
Failure of the cable or drive mechanism used to move the source racks	24 hours	30 days	12VAC5-481-2940

Event	Telephone Notification	Written Report	Regulatory Requirement
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.

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 μ Ci/g)	Limited Quantity (\$173.421)	A ₁ /A ₂ value (\$173.435)	1 rem/hr at 3 m, un-shielded (\$173.427)
Non-LSA/SCO:	Excepted	Type A	Type B ³	
Domestic or International LSA/SCO: • LSA-I solid, (liquid) ¹ • SCO-I	Excepted	IP-I	Type B ³	
• LSA-I Liquid • LSA-II Solid, (liquid or gas) ¹ • (LSA-III) ¹ • SCO-II		IP-II	Type B ³	
• LSA-II Liquid or Gas • LSA-III		IP-III	Type B ³	
Domestic (only) LSA/SCO: • LSA-I, II, III; SCO-I, II	Excepted	Strong-tight ²	DOT Spec. 7A Type A	Type B ³ NRC Type A LSA ^{3,4}

1. For entries in parentheses, exclusive use is required for shipment in an IP (e.g., shipment of LSA-I liquid in an IP-I packaging would require exclusive-use consignment)
2. Exclusive use required for strong-tight container shipments made pursuant to §173.427(b)(2)
3. Subject to conditions in Certificate, if NRC package
4. Exclusive use required, see §173.427(b)(4). Use of these packages expires on 4/1/99 (10 CFR 71.52)

Package and Vehicle Radiation Level Limits (49 CFR 173.441) ^A				
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials				
Transport Vehicle Use:	Non-Exclusive	Exclusive		
Transport Vehicle Type:	Open or Closed	Open (flat-bed)	Open w/Enclosure ^B	Closed
Package (or freight container) Limits:				
External Surface	2 mSv/hr (200 mrem/hr)	2 mSv/hr (200 mrem/hr)	10 mSv/hr (1000 mrem/hr)	10 mSv/hr (1000 mrem/hr)
Transport Index (TI) ^C	10	no limit		
Roadway or Railway Vehicle (or freight container) Limits:				
Any point on the outer surface	N/A	N/A	N/A	2 mSv/hr (200 mrem/hr)
Vertical planes projected from outer edges		2 mSv/hr (200 mrem/hr)	2 mSv/hr (200 mrem/hr)	N/A
Top of . . .		load: (200 mrem/hr)	enclosure: 2 mSv/hr (200 mrem/hr)	vehicle: 2 mSv/hr (200 mrem/hr)
2 meters from. . .		vertical planes: 0.1 mSv/hr (10 mrem/hr)	vertical planes: 0.1 mSv/hr (10 mrem/hr)	outer lateral surfaces: 0.1 mSv/hr (10 mrem/hr)
Underside	2 mSv/hr (200 mrem/hr)			
Occupied position	N/A ^D	0.02 mSv/hr (2 mrem/hr) ^E		
Sum of package TI's	50	no limit ^F		

- The limits in this table do not apply to excepted packages - see 49 CFR 173.421-426.
- Securely attached (to vehicle), access-limiting enclosure; package personnel barriers are considered as enclosures.
- For nonfissile radioactive materials packages, the dimensionless number equivalent to maximum radiation level at 1 m (3.3 feet) from the exterior package surface, in millirem/hour.
- No dose limit is specified, but separation distances apply to Radioactive Yellow-II or Radioactive Yellow-III labeled packages.
- This does not apply to private carrier wearing dosimetry if under radiation protection program satisfying 10 CFR 20 or 49 CFR 172 Subpart I.
- Some fissile shipments may have combined conveyance TI limit of 100 - see 10 CFR 71.59 and 49 CFR 173.457.

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: <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) • 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 style="text-align: center;">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 style="text-align: center;">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 style="text-align: center;">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-tight 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.

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>: <ul 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 style="border-top: 1px dashed black;"/> <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] <div style="text-align: center; margin: 5px 0;">  </div> • If a Hazardous substance in non-bulk package, the letters "RQ" in association with the proper shipping name <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 Labeling Requirements

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

Hazard Communications for Class 7 (Radioactive) Materials

Placarding Vehicles (49 CFR 172.500-560)

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

Visibility and Display of Radioactive Placard

- Placards are required to be displayed:
 - On four sides of the vehicle;
 - Visible from the direction they face, (for the front side of trucks, tractor-front, trailer, or both are authorized);
 - Clear of appurtenances and devices (e.g., ladders, pipes, tarpaulins);
 - At least 3 inches from any markings (such as advertisements) which may reduce placard's effectiveness;
 - Upright and on-point such that the words read horizontally;
 - In contrast with the background, or have a lined-border which contrasts with the background;
 - Such that dirt or water from the transport vehicle's wheels will not strike them;
 - Securely attached or affixed to the vehicle, or in a holder.
- Placard must be maintained by carrier to keep color, legibility, and visibility.

Conditions Requiring Placarding

- Placards are required for any vehicle containing a package with a RADIOACTIVE Yellow-III label.
- Placards are required for shipment of LSA or SCO required by §173.427 to be consigned as exclusive use. Examples of this category are domestic, strong-tight containers with less than an 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

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

Some Special Considerations/Exceptions for Placarding Requirements

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

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

βγ 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)

βγ: 0.4 Bq/cm² = 40 Bq/100 cm² = 1x10⁻⁵ μCi/cm² = 2200 dpm/100 cm²

α: 0.04 Bq/cm² = 4 Bq/100 cm² = 1x10⁻⁶ μCi/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: <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)	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: <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	Internal contamination limit for excepted package-empty packaging, Class 7 (Radioactive) Material, shipped in accordance with 49 CFR 173.428. Conditions include: <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> Street 5678 Jefferson Davis Highway ** Destination Arlington, VA** Zip Code 22222**	FROM: Moisture Density Measurements, Inc. ** <small>Shipper</small> Street 1234 A Street, NW ** Origin Washington, DC 20000**
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Route	No. of Units & Container Type	HM	BASIC DESCRIPTION <small>Proper Shipping Name, Hazard Class, Identification Number (UN or NA), per 172.101-172.102</small>	TOTAL QUANTITY <small>(Weight, Volume, Gallons, etc.)</small>	WEIGHT <small>(Gross to Corridor)</small>	RATE	CHARGES <small>(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)** ** SUBSTITUTE APPROPRIATE INFORMATION FOR YOUR GAUGE AND YOUR SHIPMENT	2.31 GBq (61 mCi)			

PLACARDS TENDERED: YES NO

REMIT
C.O.D. TO:
ADDRESS

Note - Where the rate is dependent on value, shippers are required to state specifically in writing the agreed or declared value of the property.
The agreed or declared value of the property is hereby specifically stated by the shipper to be not exceeding

I hereby declare that the contents of the consignment 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 this mode of transport in compliance with applicable Federal DOT (TRANSPORT) according to applicable international and national governmental regulations.

COD Amt: \$

Subject to Section 7 of the conditions, if the shipment is to be delivered to the consignee without recourse on the consignor, the consignor shall sign the following statement:
The consignor shall make delivery of the shipment without demand of freight and of other local charges.

C.O.D. FEE:
PREPAID
COLLECT \$

TOTAL CHARGES: \$

FREIGHT CHARGES
FREIGHT PREPAID Collect

RECEIVED, subject to the specifications and liability filed, limits in effect on the date of issuance of this Bill of Lading, the property described above in apparent good order, except as noted hereon, and condition of contents of packages (contents marked, consigned, and delivered as indicated above) which shall remain the sole responsibility of the consignor, and shall be delivered to the consignee in possession of the property under the contract of carriage in full and complete conformity with the contract of carriage, and shall be delivered to the consignee in full and complete conformity with the contract of carriage, and shall be delivered to the consignee in full and complete conformity with the contract of carriage.

and under the conditions and to each party of any other person in all or any part and property that may be service to be performed hereunder shall be subject to all the bill of lading terms and conditions in the governing transportation on the date of shipment.
Shipper hereby declares that he is familiar with all the bill of lading terms and conditions in the governing transportation and the bill of lading and conditions are hereby agreed to by the shipper and accepted by the carrier and the consignee.

SHIPPER	CARRIER
PER	PER
	DATE

Permanent post office address of shipper:

STYLE F65 LABELMASTER Div of American Labelmark Co., Chicago, IL 60646 312/476-0000

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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.”