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

INITIAL APPLICATION FOR A RADIOACTIVE MATERIAL LICENSE AUTHORIZING THE USE OF 12VAC5-481 PART XII IRRADIATORS

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

Instructions – Complete all items for the initial application of a Part XII Irradiator. 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, 7th Floor, 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) Name: E-mail:
, -	
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)

RSO Name:

Tel (Include area code): ( ) - x E-mail:

☐ 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**.

AND EITHER

☐ The above named individual will perform all duties and responsibilities as listed in Appendix H in VAREG 'Guidance for Commercial Radiopharmacy' and ensure proper oversight of the radiation safety program, including but not limited to, performing periodic on-site evaluations.

OR

☐ Alternative information is attached demonstrating how the listed individual will perform the duties and responsibilities and detailing how oversight of the radiation safety program will be conducted, including but not limited to, performing periodic on-site evaluations.

IRRADIATOR OPERTORS 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 ☐ Cobalt-60 ☐ Strontium-90 ☐ Cesium-137 ☐ Other Isotope (please specify):	IRRADIATOR MANUFACTURER AND MODEL NUMBER
ELEMENT AND MASS NUMBER ☐ Cobalt-60 ☐ Strontium-90 ☐ Cesium-137 ☐ Other Isotope (please specify):	IRRADIATOR MANUFACTURER AND MODEL NUMBER
MAXIMUM QUANTITY (Not to exceed either the maximum activity per source or device as specified in the Sealed Source and Device Registration Certificate)	MAXIMUM AMOUNT OF DEPLETED URANIUM (KG)
SEALED SOURCE MANUFACTURER OR DISTRIBUTOR AND MODEL NUMBER	DEVICE MANUFACTURER OR DISTRIBUTOR AND MODEL NUMBER
MAXIMUM ACTIVITY PER SOURCE FOR DRY-SOURCE STORAGE	INTENDED USE: (Specific description of use of each type of irradiator requested. A description of purposes and safety analysis to support safe use has been attached)

FINANCIAL ASSURANCE

☐ 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 1rradiators**, 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**.)

Category: Application fee enclosed (for new applications):

☐ Yes ☐ No Amount Enclosed

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

Item 12

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

SIGNATURE - Applicant Or Authorized Individual Date signed:

Print Name and Title of above signatory