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

APPLICATION FOR A NEW RADIOACTIVE MATERIAL LICENSE FOR MEDICAL USE

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

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

APPLICATION TYPE

Item 1. Type Of Application (Check box)

☐ New License

CONTACT INFORMATION

Item 2. Name and Mailing Address of Applicant

, -

Applicant's Telephone Number (Include Area Code)
( ) - x

Item 3. Person to contact regarding this application
Name:

E-mail:

Telephone Number (Include area code)
( ) - x

LOCATION OF RADIOACTIVE MATERIAL

Item 4. Address(es) Where Radioactive Material Will Be Used Or Possessed (Do not use P.O. Box)

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

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

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

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

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

Is radioactive material used at other off-site locations? ☐ Yes ☐ No

If yes, please attach an additional sheet(s) with the address(es) and a list of activities to be conducted at each location of use.

INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY

Item 5.1 Radiation Safety Officer (RSO) (Check all that apply and attach evidence of training and experience)

☐ We will provide the name of the proposed RSO and other potential designees who will be responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures. We will provide documentation showing delegation of authority to the Radiation Safety Officer.

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

AND

☐ The above named individual will perform all duties and responsibilities as listed in Appendix F of VAREG 'Guidance for Medical Use of Radioactive Material' 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.

AND ONE OF THE FOLLOWING

☐ We will provide the previous license number (if issued by VDH) or a copy of the license (if issued by the NRC or another Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO.

OR

☐ We will provide a copy of the certification(s) for the board(s) approved by VDH and as applicable to the types of use for which he or she has RSO responsibility.

AND

We will provide a written attestation, signed by a preceptor RSO, that the above training and experience as specified in **12VAC5-481-1750** has been satisfactorily completed and that the individual has achieved a level of radiation safety knowledge sufficient to independently function as a RSO. See Appendix B of VAREG 'Guidance for Medical Use of Radioactive Material' for a form that may be used for this purpose.

OR

☐ We will provide a description of the training and experience specified in **12VAC5-481-1750** demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities. See Appendix B of VAREG 'Guidance for Medical Use of Radioactive Material' for a form that may be used for this purpose.

AND

We will provide a written attestation, signed by a preceptor RSO, that the above training and experience as specified in **12VAC5-481-1750** has been satisfactorily completed and that the individual has achieved a level of radiation safety knowledge sufficient to independently function as a RSO. See Appendix B of VAREG 'Guidance for Medical Use of Radioactive Material' for a form that may be used for this purpose.

AND, IF APPLICABLE

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

Item 5.2 Authorized Users (AU) (Check all that apply and attach evidence of training and experience)

☐ We will attach a list of each proposed authorized user with the types and quantities of licensed material to be used.

AND ONE OF THE FOLLOWING FOR EACH AU

☐ We will provide the previous license number (if issued by VDH) or a copy of the license (if issued by the NRC or another Agreement State) on which the physician was specifically named as an AU for the uses requested.

OR

☐ We will provide a copy of the certification(s) for the board(s) approved by VDH and as applicable to the use requested.

AND

We will provide a written attestation, signed by a preceptor AU, that the training and experience as specified in **12VAC5-481-1910; 12VAC5-481-1940; 12VAC5-481-1960; 12VAC5-481-1980; 12VAC5-481-1990; 12VAC5-481-2000; 12VAC5-481-2001; 12VAC5-481-2010; 12VAC5-481-2030; 12VAC5-481-2040**, as applicable, has been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized user. See Appendix B of VAREG 'Guidance for Medical Use of Radioactive Material' for a form that may be used for this purpose.

OR

☐ We will provide a description of the training and experience as specified in **12VAC5-481-1910; 12VAC5-481-1940; 12VAC5-481-1960; 12VAC5-481-1980; 12VAC5-481-1990; 12VAC5-481-2000; 12VAC5-481-2001; 12VAC5-481-2010; 12VAC5-481-2030; 12VAC5-481-2040**, as applicable, demonstrating that the proposed AU is qualified by training and experience for the use requested. See Appendix B of VAREG 'Guidance for Medical Use of Radioactive Material' for a form that may be used for this purpose.

AND

We will provide a written attestation, signed by a preceptor AU, that the above training and experience as specified in **12VAC5-481-1910; 12VAC5-481-1940; 12VAC5-481-1960; 12VAC5-481-1980; 12VAC5-481-1990; 12VAC5-481-2000; 12VAC5-481-2001; 12VAC5-481-2010; 12VAC5-481-2030; 12VAC5-481-2040** as applicable, has been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized user. See Appendix B of VAREG 'Guidance for Medical Use of Radioactive Material' for a form that may be used for this purpose.

AND, IF APPLICABLE

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

Item 5.3 Authorized Nuclear Pharmacist (ANP) (Check all that apply and attach evidence of training and experience)

☐ Not applicable

OR

☐ We will provide the name(s) of the authorized nuclear pharmacist(s).

AND ONE OF THE FOLLOWING FOR EACH ANP

☐ We will provide the previous license number (if issued by VDH) or a copy of the license (if issued by the NRC or another Agreement State) on which the individual was specifically named ANP.

OR

☐ We will provide a copy of the certification(s) for the radiopharmacy board(s) approved by VDH.

AND

We will provide a written attestation, signed by a preceptor ANP, that the training and experience as specified in **12VAC5-481-1770** has been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist. See Appendix B of VAREG 'Guidance for Medical Use of Radioactive Material' for a form that may be used for this purpose.

OR

☐ We will provide a description of the training and experience specified in **12VAC5-481-1770** demonstrating that the proposed ANP is qualified by training and experience. See Appendix B of VAREG 'Guidance for Medical Use of Radioactive Material' for a form that may be used for this purpose.

AND

We will provide a written attestation, signed by a preceptor ANP, that the training and experience as specified in **12VAC5-481-1770** has been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist. See Appendix B of VAREG 'Guidance for Medical Use of Radioactive Material' for a form that may be used for this purpose.

AND, IF APPLICABLE

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

Item 5.4 Authorized Medical Physicist (AMP) (Check all that apply and attach evidence of training and experience)
COMPLETE ONLY IF REQUESTING LICENSE AUTHORIZATION FOR: HDR, GAMMA STEREOTACTIC RADIOSURGERY UNIT, TELETHERAPY OR OPHTHALMIC USE

☐ Not applicable

OR

☐ We will provide the name(s) of the authorized medical physicist(s).

AND ONE OF THE FOLLOWING FOR EACH AMP

☐ We will provide the previous license number (if issued by VDH) or a copy of the license (if issued by the NRC or another Agreement State) on which the individual was specifically named AMP.

OR

☐ We will provide a copy of the certification(s) for the board(s) approved by VDH.

AND

We will provide a written attestation, signed by a preceptor AMP, that the training and experience as specified in **12VAC5-481-1760** has been completed and the individual has achieved a level of competency sufficient to function independently as an authorized medical physicist. See Appendix B of VAREG 'Guidance for Medical Use of Radioactive Material' for a form that may be used for this purpose.

OR

☐ We will provide a description of the training and experience specified in **12VAC5-481-1760** demonstrating that the proposed AMP is qualified by training and experience. See Appendix B of VAREG 'Guidance for Medical Use of Radioactive Material' for a form that may be used for this purpose.

AND

We will provide a written attestation, signed by a preceptor AMP, that the above training and experience as specified in **12VAC5-481-1760** has been completed and the individual has achieved a level of competency sufficient to function independently as an authorized medical physicist. See Appendix B of VAREG 'Guidance for Medical Use of Radioactive Material' for a form that may be used for this purpose.

AND, IF APPLICABLE

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

TRAINING FOR WORKERS

Item 6 Training For Individuals Working In Or Frequenting Restricted Areas (Check one box)

☐ We will follow the training programs described in Appendix H of VAREG 'Guidance for Medical Uses of Radioactive Material'.

OR

☐ We will develop and implement and maintain a training program that will meet the criteria in the section titled 'Training for Individuals Working in or Frequenting Restricted Areas' of VAREG 'Guidance for Medical Use of Radioactive Material'. (Description is attached)

RADIOACTIVE MATERIAL

Type of Use – Check Box if Use is Desired	Chemical and Physical Form	Maximum Amount (Curies)	Sealed Source Manufacturer or Distributor Model Number	Device Manufacturer or Distributor Model Number
☐ Use of Radioactive Material for Certain In-Vitro Clinical or laboratory testing if maximum activity exceeds 200 µCi **(12VAC5-481-430 G)**	Any	As needed	N/A	N/A
☐ Use of Calibration, Transmission, and Reference Sources not included in **12VAC5-481-1830** (e.g., bone densitometry sources, fluorine-18 calibration sources)	Attach a detailed description of the radioactive material and intended use.		N/A	N/A
☐ Unsealed Radioactive Material for Uptake, Dilution and Excretion Studies for Which a Written Directive is not Required (**12VAC5-481-1900**)	Any	As needed	N/A	N/A
☐ Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is not Required (**12VAC5-481-1920**)	Any	As needed	N/A	N/A
☐ Unsealed Radioactive Material for Which a Written Directive is Required (**12VAC5-481-1950**)	Any		N/A	N/A
☐ Unsealed Radioactive Material for Which a Written Directive is Required Specific radiopharmaceuticals (**12VAC5-481-1950**)	For this type of use attach a detailed description of radiopharmaceutical, form, route of administration and therapeutic use.		N/A	N/A
☐ Sources for Manual Brachytherapy (**12VAC5-481-2010**)	Sealed Source			
☐ Sources for Manual Brachytherapy – Ophthalmic Use Only (**12VAC5-481-2010**)	Sealed Source			
☐ Sealed Sources for Diagnosis (**12VAC5-481-2020**)	Sealed Source			
☐ Sealed Source(s) in a Device for Therapy – Teletherapy Unit (**12VAC5-481-2040**)	Sealed Source			
☐ Sealed Source(s) in a Device for Therapy – Remote Afterloader Unit (**12VAC5-481-2040**)	Sealed Source			
☐ Sealed Source(s) in a Device for Therapy – Gamma Stereotactic Radiosurgery Unit (**12VAC5-481-2040**)	Sealed Source			
☐ Other Medical Use of Radioactive Material or Radiation from Radioactive Material (e.g. Emerging Technology) (**12VAC5-481-2060**)	For this type of use attach a detailed description of the radioactive material and intended use			
☐ Non-medical use of radioactive material	Attach a detailed description of the radioactive material and intended use.			

Item 7.2 Recordkeeping for Decommissioning and Financial Assurance

The applicant is not required to submit proof of recordkeeping for decommissioning and financial assurance during the licensing phase. This matter will be examined during an inspection.

FACILITIES

Item 8.1 Facilities Diagram (Check box and attach requested information.)

☐ We will submit the information in the section titled 'Facilities Diagram' in VAREG 'Guidance for Medical Use of Radioactive Material'.

Item 8.2 Radiation Monitoring Instruments (Check all that apply)

☐ We will identify the instrument type, sensitivity, range for each type of radiation detected and state whether the instrument will be used for 'measuring' or 'detection'. Additionally if only one survey instrument is to be used we will describe what is done when the survey instrument is being calibrated or repaired.

AND

☐ We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.

AND

☐ We will provide a description of the instrumentation (e.g. gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys or leak testing and analysis.

AND ONE OF THE FOLLOWING

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

OR

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

Item 8.3 Dose Calibrator And Other Equipment Used To Measure Dosages Of Unsealed Radioactive Material (Check all that apply)

☐ Not applicable. (Will only use unit doses or no unsealed radioactive material use)

OR

☐ We will identify the instrument type, manufacturer, and model number. Additionally, if only one dose calibrator is possessed, we will describe what is done when the dose calibrator is being calibrated or repaired.

AND

☐ Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.

Item 8.4 Dosimetry Equipment – Calibration And Use (Check all that apply)

COMPLETE THIS SECTION ONLY IF REQUESTING LICENSE AUTHORIZATION FOR: HDR, GAMMA STEREOTACTIC RADIOSURGERY UNIT, TELETHERAPY OR BRACHYTHERAPY USE

☐ N/A

OR

☐ We will calibrate dosimetry equipment in accordance with the requirements in 12VAC5-481-2040.

AND

☐ We have developed and will implement a written calibration procedure for a therapy sealed source that meets the requirements in 12VAC5-481-2010 and 12VAC5-481-2040 (as applicable to the type of medical use requested).

AND

☐ We will identify the dosimetry system, manufacturer and model number.

Item 8.5 Other Equipment And Facilities (Check box and attach requested information)

☐ A detailed description of additional equipment and facilities available for the safe use and storage of radioactive materials requested is attached.

RADIATION PROTECTION PROGRAM

Item 9.1 Audit Program

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

Item 9.2 Occupational Dose (Check all that apply)

☐ We will provide a description of facilities and equipment used for monitoring occupational exposure. (Description is attached)

AND ONE OF THE FOLLOWING

☐ We will follow the procedures in Appendix L of VAREG 'Guidance for Medical Use of Radioactive Material' for monitoring occupational dose.

OR

☐ We have developed and will implement written procedures for monitoring occupational dose in accordance with **12VAC5-481-630** that meets the requirements in **12VAC5-481 'Virginia Radiation Protection Regulations', Part IV 'Standards for Protection Against Radiation.'** (Procedures are attached)

Item 9.3 Public Dose

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

Item 9.4 Minimization Of Contamination (Check one box)

☐ We will follow the cleanup procedures from Appendix R, Tables 9 and 10, of VAREG 'Guidance for Medical Use of Radioactive Material' to minimize the amount of radioactive contamination and radioactive waste generated at our facility.

OR

☐ We will develop, implement and maintain procedures to minimize the amount of radioactive contamination and radioactive waste generated at our facility. (Procedures are attached.)

Item 9.5 Operating And Emergency Procedures

No response is required, in this license application; however the licensee's operating and emergency procedures will be examined during an inspection.

Item 9.6 Material Receipt And Accountability (Check one box)

☐ Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license. Records of inventories will be maintained for 5 years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer's name and model numbers, location, individual performing inventory and the date of the inventory.

OR

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

Item 9.7 Ordering And Receiving (Check one box)

☐ We will develop, implement and maintain ordering and receiving procedures that will meet the criteria in the section titled 'Ordering and Receiving' of VAREG 'Guidance for Medical Use of Radioactive Material'. (Procedures are attached)

OR

☐ We will follow procedures for ordering and receiving in accordance with Appendix O of VAREG 'Guidance for Medical Use of Radioactive Material'.

Item 9.8 Opening Packages

No response is required, in this license application; however the licensee's package opening procedure will be examined during an inspection.

Item 9.9 Leak Test (Check one box)

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

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

Organization Name: _____ License Number: _____

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

OR

☐ We will perform our own leak testing and sample analysis. We will follow the procedures in Appendix Q of VAREG 'Guidance for Medical Use of Radioactive Material'.

OR

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

Item 9.10 Area Surveys (Check one box)

☐ We will develop, implement and maintain procedures for area surveys that will meet the criteria in the section titled 'Area Surveys' in VAREG 'Guidance for Medical Use of Radioactive Material'. (Procedures are attached)

OR

☐ We will follow the procedures for area survey in Appendix R of VAREG 'Guidance for Medical Use of Radioactive Material'.

Item 9.11 Procedures For Administration of Radioactive Material Requiring A Written Directive (Check one box)

☐ We will develop, implement and maintain procedures for administration of radioactive material requiring a written directive that will meet the criteria in the section titled 'Procedures for Administrations Requiring a Written Directive' in VAREG 'Guidance for Medical Use of Radioactive Material'.

OR

☐ Not Applicable.

Item 9.12 Safe Use Of Unsealed Radioactive Material (Check one box)

☐ We will develop, implement and maintain procedures for the safe use of unsealed radioactive material, that will meet the criteria in the section titled 'Safe Use of Unsealed Radioactive Material' in VAREG 'Guidance for Medical Use of Radioactive Material'. (Procedures are attached)

OR

☐ We will follow the procedures for the safe use of unsealed radioactive material in Appendix T of VAREG 'Guidance for Medical Use of Radioactive Material'.

OR

☐ Not Applicable.

Item 9.13 Maintenance Of Therapy Devices Containing Sealed Sources (Check all that apply)

☐ Not Applicable. (No therapy devices containing sealed sources)

OR

☐ We will contract with personnel who are licensed by VDH, the NRC or another Agreement State to perform maintenance and repair services on the specific therapy device(s) possessed by the licensee.

OR THE FOLLOWING THREE CONDITIONS MUST BE MET

☐ We will name the proposed employee or employees and types of maintenance and repair requested.

AND

☐ We will provide a description of the training and experience demonstrating that the proposed employee or employees is/are qualified by training and experience for the use requested.

AND

☐ We will provide a copy of the manufacturer's training certification and an outline of the training.

Item 9.14 Spill Procedures (Check one box)

☐ We will develop, implement and maintain procedures for response to spills of radioactive material. (Procedures are attached.)

OR

☐ We will follow procedures for response to spills of radioactive material in accordance with Appendix N of VAREG 'Guidance for Medical Use of Radioactive Material'.

OR

☐ Not Applicable. (Unsealed radioactive material not used)

Item 9.15 Emergency Response For Sealed Sources Or Devices Containing Sealed Sources (Check one box)

☐ We will develop, implement and maintain procedures for emergency response for sealed sources or devices containing sealed sources. (Procedures are attached)

OR

☐ Not Applicable. (Brachytherapy sources, high activity sealed sources or devices containing sealed sources not used)

Item 9.16 Release of Patients Or Human Research Subjects (Check one box)

☐ We will develop, implement and maintain procedures for release of patients or human research subjects that will meet the criteria in the section titled 'Release of Patients or Human Research Subjects' in VAREG 'Guidance for Medical Use of Radioactive Material'. (Procedures are attached)

OR

☐ We will follow the procedures for release of patients or human research subjects in Appendix U of VAREG 'Guidance for Medical Use of Radioactive Material'.

OR

☐ Not applicable. (Studies only performed under **12VAC5-481-1900** & **12VAC5-481-1920**)

Item 9.17 Mobile Medical Service (Check one box)

☐ We will provide the information requested, along with any procedures mentioned in Appendix V of VAREG 'Guidance for Medical Use of Radioactive Material'. (Procedures are attached)

OR

☐ Not applicable.

Item 9.18 Transportation

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

Note: Before offering a Type B package for shipment, a licensee needs to have registered as a user of the package and obtained the agency's approval of its QA Program. Alternatively, the licensee may choose to transfer possession of radioactive material to a manufacturer (or distributor) (or service licensee) with a VDH, NRC or another Agreement State license who then acts as the shipper.

Item 9.19 Sealed Source Inventory
Item 9.20 Records of Dosages and Use of Brachytherapy Source
Item 9.21 Safety Procedures For Treatments Where Patients Are Hospitalized
Item 9.22 Recordkeeping
Item 9.23 Reporting

No response is needed during the licensing process; these issues will be reviewed during inspection.

WASTE MANAGEMENT

Item 10 Waste Management (Check all that apply)

☐ We will follow the waste procedures published in Appendix X of VAREG 'Guidance for Medical Use of Radioactive Material'.

AND / OR

☐ We will use: ☐ Decay-In-Storage, or ☐ Disposal of Liquids Into Sanitary Sewerage waste procedures that are published in Appendix X of VAREG 'Guidance for Medical Use of Radioactive Material'.

AND / OR

☐ We will provide procedures for waste collection, storage and disposal by any of the authorized methods described in Item 10 'Waste Management' of VAREG 'Guidance for Medical Use of Radioactive Material'. We will contact VDH for guidance to obtain approval of any method(s) of waste disposal other than those discussed in Item 10 'Waste Management' of VAREG 'Guidance for Medical Use of Radioactive Material'. (Procedures are attached)

LICENSE FEES

Item 11 License Fees (Refer to **12VAC5-490**.)

Application Fee Enclosed (For new applications):

☐ 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