

Application for Radioactive Material License for Medical Use

The Wisconsin Department of Health Services (DHS) 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 WISREG "Guidance for Medical Use of Radioactive Material." No response is required for item numbers not included in this application; however, these items may be examined during an inspection. Retain one copy and submit original of the entire application to DHS, PO Box 2659, Madison, WI 53701-2659 or DHSRadioactiveMaterials@dhs.wisconsin.gov.

The application certification must be signed by senior representatives of the applicant. Representatives signing an application must be authorized to make binding commitments and sign official documents on behalf of the applicant. The department will return all unsigned applications for proper signature.

Certification

I hereby certify that this application was prepared in conformance with Chapter DHS 157 "Radiation Protection" and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.

Signature – Authorized Senior Representative

Print name and title of above signatory

Date signed

Optional: Correspondence authority

The designee named here has approval to submit amendment requests concerning this Radioactive Materials License. I understand that license renewal applications must be signed by a member of upper management. I have delegated correspondence authority for matters pertaining to our Radioactive Materials License to:

Full name of designee(s)

Signature – **Authorized** Senior Representative

Date signed

Application type

Item 1. Type of application (Check one box)

☐ New license ☐ Renewal, License number: _____

Contact information

Item 2. Name and mailing address of applicant

Item 3. Person to contact regarding this application

Applicant's phone number (Include area code)

Contact's phone number (Include area code)

Location of radioactive material

Item 4. Address(es) where radioactive material will be used or possessed (Do not use PO Box)

Address

Phone number (Include area code)

Address	Phone number (Include area code)
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Address	Phone number (Include area code)
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Address	Phone number (Include area code)
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Is radioactive material used at other off-site locations? ☐ Yes ☐ No

If yes, 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.

Name: _____

Phone number (Include area code)

And one of the following

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

Or

- ☐ We will provide documentation of RSO training and experience.

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 DHS) or a copy of the license (if issued by the NRC or an Agreement State) on which the physician was specifically named as an AU for the uses requested.

Or

- ☐ We will provide documentation of training and experience which meets the applicable authorized user training requirements.

Item 5.3 Authorized Medical Physicist (AMP) (Check all that apply and attach evidence of training and experience)

- ☐ Not applicable (HDR, Gamma Stereotactic Radiosurgery, Teletherapy or Ophthalmic Use not requested)
- ☐ We will provide the name(s) of the authorized medical physicist(s).
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And one of the following for each AMP

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

Or

☐ We will provide documentation of training and experience which meets the applicable authorized medical physicist training requirements.

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 WISREG "Guidance for Medical Uses of Radioactive Material" Revision 3.

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 WISREG "Guidance for Medical Use of Radioactive Material" Revision 3 (Description is attached)

Radioactive material**Item 7.1 Purpose(s) for which licensed radioactive material will be used.** (Attach additional pages if necessary)

	Type of use – Check box if use is desired	Maximum amount (Curies)	Notes
<input type="checkbox"/>	Unsealed Radioactive Material for Uptake, Dilution and Excretion Studies, s. DHS 157.63 (1)	As needed	
<input type="checkbox"/>	Unsealed Radioactive Material for Imaging and Localization Studies, s. DHS 157.63 (2)	As needed	
<input type="checkbox"/>	Unsealed Radioactive Material for Which a Written Directive is Required, s. DHS 157.64 (1)		
<input type="checkbox"/>	Sources for Manual Brachytherapy s. DHS 157.65 (1)		Provide Sealed Source and Device Registration sheet numbers for requested sources and devices
<input type="checkbox"/>	Sealed Sources for Diagnosis s. DHS 157.66 (1)		
<input type="checkbox"/>	Sealed Source(s) in a Device for Therapy s. DHS 157.67 (1)		
<input type="checkbox"/>	Other Medical Use of Radioactive Material or Radiation from Radioactive Material (e.g. Emerging Technology) s. DHS 157.70 For Radioactive Seed Localization, Ge-68/Ga-68 generator, and Y-90 microspheres sample commitments contact DHSRadioactiveMaterials@dhs.wisconsin.gov		Attach a detailed description of the radioactive material, intended use, and additional licensing commitments.

<input type="checkbox"/>	Use of Calibration, Transmission, and Reference Sources not included in s. DHS 157.62 (4)		Attach a detailed description of the radioactive material and intended use.
<input type="checkbox"/>	Non-medical use of radioactive material		Attach a detailed description of the radioactive material and intended use.

Facilities and equipment

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

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

Item 8.2 Radiation monitoring instrumentation (Check all that apply)

- ☐ We will provide a description of the instrumentation that will be used to perform required surveys or leak testing and analysis. 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 instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.

And one of the following

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

Or

- ☐ We will follow survey meter calibration procedures in Appendix I of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

Item 8.4 Dosimetry equipment – Calibration and use (Check all that apply)

- ☐ Not applicable. (Will not use sealed sources for therapy)

Or

- ☐ We have developed and will implement a written calibration procedure for a therapy sealed source that meets the requirements in s. DHS 157.65(6) and s. DHS 157.67(6-12) (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 9.2 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 WISREG "Guidance for Medical Use of Radioactive Material" Revision 3 for monitoring occupational dose.

Or

- ☐ We have developed and will implement written procedures for monitoring occupational dose in accordance with s. DHS 157.21 and that meets the requirements in Chapter DHS 157, Subchapter III. (Procedures are attached)

Item 9.4 Minimization of contamination (Check one box)

- ☐ We will follow the cleanup procedures from Appendix R, Tables 8 and 9, of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3 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 9.6 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.

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 entitled 'Ordering and Receiving' of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3. (Procedures are attached)

Or

- ☐ We will follow procedures for ordering and receiving in Appendix O of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

Item 9.9 Leak test (Check one box)

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

Or

- ☐ We will perform our own leak testing and sample analysis. We will follow the procedures in Appendix Q of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

Or

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

Item 9.10 Area and personnel surveys (Check one box)

- ☐ We will develop, implement and maintain procedures for radiation surveys that will meet the criteria in the section titled 'Area and Personnel Surveys' in WISREG "Guidance for Medical Use of Radioactive Material" Revision 3. (Procedures are attached)

Or

- ☐ We will follow the procedures for area and personnel surveys in Appendix R of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

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 entitled 'Procedures for Administrations Requiring a Written Directive' in WISREG "Guidance for Medical Use of Radioactive Material."

And if applicable

- ☐ We are requesting the approval to use electronic documents and signatures for written directives, quality assurance, and treatment planning where users approve documents with a unique username, password, and/or time-date stamp.

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 WISREG "Guidance for Medical Use of Radioactive Material" Revision 3 (Procedures are attached.)

Or

- ☐ We will follow the procedures for the safe use of unsealed radioactive material in Appendix T of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

Or

- ☐ Not Applicable. (Unsealed radioactive material not used)

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 DHS, the NRC or an Agreement State to perform maintenance and repair services on the specific therapy device(s) possessed by the licensee.

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 WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

Or

- ☐ Not Applicable. (Unsealed radioactive material not used)
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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 follow the procedures for release of patients or human research subjects in Nuclear Regulatory Commission's Regulatory Guide 8.39 "Release of Patients Administered Radioactive Material" Revision 1. References in the Regulatory Guide to the NRC's regulations (Title 10 of the Code of Federal Regulations) shall be interpreted as the respective DHS Administrative Code (DHS 157). Where the Regulatory Guide says "should" we will implement this as saying "shall."

Or

- ☐ We will develop, implement and maintain procedures for release of patients or human research subjects that will address the considerations in the Nuclear Regulatory Commission's Regulatory Guide 8.39 "Release of Patients Administered Radioactive Material" Revision 1. (Procedures are attached)

Or

- ☐ Not applicable. (Studies only performed under s. DHS 157.63(1) & (2))

Item 9.17 Mobile medical service (Check one box)

- ☐ We will provide the information requested, along with any procedures mentioned in Appendix V of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3. (Procedures are attached)

Or

- ☐ Not applicable.

Waste management**Item 10 Waste management** (Check all that apply)

- ☐ We will follow the waste procedures published in Appendix X of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

Or

- ☐ We will provide procedures for waste collection, storage and disposal by any of the authorized methods described in Item 10 'Waste Management' of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3. We will contact DHS for guidance to obtain approval of any method(s) of waste disposal other than those discussed in Item 10 'Waste Management' of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3. (Procedures are attached)

Fees**Item 11 License fees** (Refer to Wisconsin Administration Code DHS 157.10)

Category:

Application fee enclosed (For new applications only):

☐ Yes ☐ No Amount Enclosed: \$