



**APPLICATION FOR A RADIOACTIVE MATERIAL LICENSE
 AUTHORIZING THE MEDICAL USE OF RADIOACTIVE MATERIALS**

INSTRUCTIONS: Refer to R-11 (7C) for a detailed explanation of the requirements for completing this application. This application must be signed and dated. An application fee in the amount specified in Part 12 of the *Colorado Rules and Regulations Pertaining to Radiation Control* must accompany an application for a new license. Email the completed application and attachments to CDPHE_hmradmat@state.co.us. Mail the fee payment (and the application and attachments, if they cannot be submitted electronically) to the Colorado Department of Public Health and Environment, Radiation Management Program, HMWMD-B2, 4300 Cherry Creek Drive South, Denver, Colorado 80246-1530. All radioactive materials licenses are issued in accordance with the general requirements contained in the State of Colorado *Rules and Regulations Pertaining to Radiation Control* and Title 25, Article 11, CRS.

1. Application for: New License: ____ (fee required) Renewal: ____ Amendment: ____
 Current License No: _____ Expiration Date: _____
2. Applicant Name: _____
3. Mailing Address: _____
 City: _____ State: _____ Zip: _____
4. Management Contact: _____ Phone: _____
 E-mail Address: _____ Fax: _____
5. Facility Address: _____
 City: _____ State: _____ Zip: _____
6. Billing Contact (if different from above): _____
 Phone: _____ Address: _____
 City: _____ State: _____ Zip: _____
 E-mail Address: _____ Fax: _____
7. Radiation Safety Officer: _____ Phone: _____
 E-mail Address: _____ Fax: _____
8. Alternate Radiation Safety Officer(s):

The above designated Radiation Safety Officer (RSO) and designated alternate RSO(s) are individuals who have been appointed by the applicant named in Item 2 and have the responsibilities described in Part 7, Section 7.7 of the Regulations. **The applicant will maintain a signed statement from each individual performing the duties of Radiation Safety Officer documenting their agreement to accept responsibilities in accordance with the requirements of Part 7, Section 7.7.2. Please provide a copy of the signed agreement with the application.**

9. Check to the left to indicate each type of radioactive material usage to be performed at your facility. If an item is not applicable to your program, indicate with N/A in the blank provided.

- A. Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies (7.30)
- B. Unsealed Radioactive Material for Imaging and Localization Studies (7.32)
- C. Unsealed Radioactive Material for PET (7.32)
- D. Human Research (7.3.2)
- E. Generators (Mo-99/Tc-99m or Sr-82/Rb-82) (7.33)
- F. Depleted uranium for shielding
- G. Radioactive Aerosols and Gases (7.34)
- H. Any Unsealed Radioactive Material Requiring a Written Directive (7.36.2)
- I. Oral Administration of ≤ 33 mCi Na I-131 Requiring a Written Directive (7.36.3)
- J. Oral Administration of > 33 mCi Na I-131 Requiring a Written Directive (7.36.4)
- K. Unsealed Radioactive Material for Parenteral Use Requiring a Written Directive (7.36.5)
- L. Sealed Radioactive Sources for Diagnosis (7.40)
- M. Sealed Sources for Manual Brachytherapy (7.42)
- N. Sr-90 Sources for Ophthalmic Uses (7.42.3)
- O. Sealed Source(s) in a Remote Afterloader Unit (LDR and MDR) (7.48)
- P. Sealed Source(s) in a Remote Afterloader Unit (HDR) (7.48)
- Q. Sealed Source(s) in a Teletherapy Unit (7.48)
- R. Sealed Sources Gamma Stereotactic Radiosurgery (GSR) Unit (7.48)
- S. Microspheres (7.62)
- T. GliaSite Brachytherapy Device (7.62)
- U. Iodine-125 or Palladium-103 Low Dose Rate Brachytherapy Seeds used for Radioactive Seed Localization (RSL) of non-palpable lesions (7.62)
- V. Leksell Perfexion Gamma Stereotactic Radiosurgery Unit (7.62)
- W. Any Other Medical Uses of Radioactive Material (7.62)
- X. Calibration of Survey Instruments (7.17)
- Y. Mobile Nuclear Medicine Services (7.27)
- Z. Check, Calibrations, and QC of Dose Calibrators and Imaging Equipment (7.19)

10. Attach a detailed diagram of each facility where radioactive materials will be used and stored.
11. Attach calculations and/or survey results to demonstrate compliance with dose limits for members of the public at all storage and use locations.
12. Attach a list of radioactive sources to be used for reference and/or calibration, including those sources utilized within imaging equipment. Specify the manufacturer, model number, radionuclide, and the maximum activity of each source.
13. Attach copies of applicable board certifications, signed preceptor statements, and any other needed documentation to demonstrate that each designated Radiation Safety Officer (RSO) and alternate RSO satisfies the requirements of Part 7, Appendix 7A. If the license will include multiple locations of use, identify the individual who will be the designated RSO for each facility.
14. Attach a listing of the name(s) of each person to be designated as an authorized user of radioactive materials on the license. Specify the type of authorization to be granted for each individual and provide copies of applicable board certifications, signed preceptor statements, current medical licenses, and any other needed documentation to demonstrate that the individual meets the applicable requirements of Part 7, Appendix 7.D through Appendix 7.M.
15. Attach a completed Medical Physicist Authorization request form for each person to be designated as an authorized medical physicist on the license. Specify the type of authorization to be granted for each individual and provide copies of applicable board certifications, signed preceptor statements, and any other needed documentation to demonstrate that the individual meets the applicable requirements of Part 7, Appendix 7.B.
16. Attach a listing of the name(s) of each person to be designated as an authorized nuclear pharmacist on the license. Provide copies of applicable board certifications, signed preceptor statements, and any other needed documentation to demonstrate that the individual meets the applicable requirements of Part 7, Appendix 7.C.
17. **Operating Procedures and Provisions for the Radiation Protection Program**
Attach a copy of your written operating procedures and provisions addressing each of the applicable items. Check to the left to indicate each set of procedures attached. If an item is not applicable to your program, indicate with N/A in the blank provided.
 - A. ___ Receipt of Radioactive Materials and Opening Packages (4.32)
 - B. ___ Storage of Radioactive Materials and Material Security (3.9.2)
 - C. ___ Routine Surveys for Contamination (4.15.1, 4.17, and 7.25)
 - D. ___ Radioactive Waste Disposal (4.33 and 7.29)
 - E. ___ Spills and Emergency Procedures (4.5.2)
 - F. ___ Leak Testing Sealed Sources (4.16, 7.20)

- G. ____ Training and Instruction to Workers (3.9.1, 4.5.2, 7.10, and 10.3)
- H. ____ Dosimetry Program (4.18)
- I. ____ Radiation Protection Program, ALARA Provisions, Annual Program Audit (4.5, 7.7)
- J. ____ The Authority, Duties, and Responsibilities of the Radiation Safety Officer (7.7.4)
- K. ____ Radiation Safety Committee (7.8)
- L. ____ Procedures for Administrations Requiring a Written Directive (7.12)
- M. ____ Quality Control of Diagnostic Equipment (7.15)
- N. ____ Dose Calibrator Tests of Constancy, Linearity, Accuracy, and Geometry (7.16)
- O. ____ Calibration of Survey Instruments (7.17)
- P. ____ Determination of Dosages of Radioactive Material for Medical Use (7.18)
- Q. ____ Release of Individuals Who Have Been Administered Radioactive Drugs (7.26)
- R. ____ Mobile Nuclear Medicine Service (7.27)
- S. ____ Procedures and Instructions for Generator Use
- T. ____ Safety Procedures and Instructions for a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit (7.51)
- U. ____ Procedures and Instructions for Spot Checks of Remote Afterloader Units (7.59 , 7.60)
- V. ____ Procedures and Instructions for Spot Checks of Teletherapy Units (7.58)
- W. ____ Procedures and Instructions for Spot Checks of Stereotactic Radiosurgery Units (7.61)
- X. ____ Procedures and Instructions for Microspheres
- Y. ____ Procedures and Instructions for GliaSite Brachytherapy Device
- Z. ____ Procedures and Instructions for I-125 or Pd-103 Low Dose Rate Brachytherapy Seeds used for Radioactive Seed Localization (RSL) of non-palpable lesions
- AA. ____ Procedures and Instructions for Leksell Perfexion Gamma Stereotactic Radiosurgery Unit
- BB. ____ Procedures and Instructions for Any Other Medical Uses of Radioactive Material

18. **Survey Instruments:** Attach a description of the survey instrument(s) that will routinely be available for use at your facility. The description should include the specific instrument manufacturer, model, probe/detector type, and the detection range.

COMMITMENTS:

- C.1 All uses of radioactive materials will be in accordance with the provisions of the State of Colorado *Rules and Regulations Pertaining to Radiation Control*, Part 4, "Standards for Protection Against Radiation", Part 7, "Use of Radionuclides in The Healing Arts", and Part 10, "Notices, Instructions and Reports to Workers: Inspections", and Part 17, "Transportation of Radioactive Material".
- C.2 Each person who will fulfill the duties of a nuclear medicine technologist will meet the applicable requirements of Part 7, Appendix 7.N. for training and experience. The radiation safety officer will maintain copies of applicable board certifications, signed preceptor statements, and any other needed documentation to demonstrate appropriate training and experience for these individuals. These documents shall be available for review by the Department during facility inspection.
- C.3 Each person who will fulfill the duties of a radiation therapy technologist will meet the applicable requirements of Part 7, Appendix 7.O. for training and experience. The radiation safety officer will maintain copies of applicable board certifications, signed preceptor statements, and any other needed documentation to demonstrate appropriate training and experience for these individuals. These documents shall be available for review by the Department during facility inspection.
- C.4 The applicant will ensure that each nuclear medicine technologist and radiation therapy technologist is adequately supervised by an Authorized User specifically named on the license. If the applicant does not have one or more Authorized Users who work at the designated use location(s) on a daily basis, then the applicant shall establish and maintain a procedure for ensuring adequate supervision of the technologists and for documenting that supervision.
- C.5 The applicant will establish and implement written procedures designed to prevent: the administration of the wrong radioactive drug to an individual; the administration of a radioactive drug by the wrong route of administration; the administration of a radiation dose or radioactive drug to the wrong individual; and, the administration of a radiation dose or dosage delivered by the wrong mode of treatment.
- C.6 The applicant will maintain documentation as required by the Regulations, the license, and this application for review by the Department.
- C.7 The applicant named in Item 2 acknowledges its responsibility for control and disposal of all radioactive materials possessed under a radioactive materials license issued by the Department. The applicant further acknowledges that the requirements of the license and the Regulations will remain in effect until termination of the license by the Department, even if the license has expired.

CERTIFICATE

The applicant and each official executing this certificate on behalf of the applicant named in Item 2, certify that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief. The applicant agrees to abide by all commitments herein, and the requirements of the radioactive materials license and the State of Colorado *Rules and Regulations Pertaining to Radiation Control*.

Management Signature: _____ Date: _____

Typed or Printed Name: _____

Title of Official: _____

Radiation Safety Officer Signature: _____ Date: _____

Typed or Printed Name: _____