



INSTRUCTIONS FOR THE COMPLETION OF A LICENSE APPLICATION FOR THE MEDICAL USE OF RADIOACTIVE MATERIAL, FORM R-12 (7C)

Form R-12 (7C) is to be used for all new license applications and for the renewal of an existing Radioactive Material License for medical use. An **application fee** payment must accompany each **new** license application. Please review Fee Category 7 in the appendix of Part 12 of the Regulations for the current fee amount. No application fee is charged for the timely renewal of an existing license.

Applications to amend an existing radioactive materials license do not normally require the completion of a form. To amend a license, submit a letter to the Department detailing the requested changes and provide any necessary supporting information. Ensure that the letter is signed by an officer of the company having the authority to make commitments on behalf of the applicant/licensee.

The submission of an incomplete application may delay the issuance of the license because of the correspondence necessary to obtain complete information. Pursuant to Sections 12.2 and 12.4.1.5 of the Regulations, the Department may consider any application abandoned if the Department does not receive a reply within forty-five (45) days to its most recent request for additional information.

Licensees may e-mail the completed application and attachments to CDPHE_hmradmat@state.co.us and 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. A copy of these documents must be retained by the applicant.

Throughout the application and these instructions, there are numerous references to the Regulations. These refer to the State of Colorado *Rules and Regulations Pertaining to Radiation Control*. Specific provisions of the Regulations may be identified by reference to the section number such as “4.6” which references Part 4, Section 4.6, Occupational Dose Limits for Adults.

- Item 1.** If this application is for a new license write “new” and include with your application an application fee payment. Please review Fee Category 7 in the appendix of Part 12 of the Regulations for the current fee amount. If this application is for the renewal or amendment of an existing license, indicate the license number and expiration date for your current license. No application fee is required for an amendment or the renewal of your existing radioactive materials license.
- Item 2.** The “Applicant” is the organization or person legally responsible for possession and use of the radioactive material specified in the application. This will usually be the hospital's or clinic's name.

- Item 3.** Indicate the applicant's mailing address inside the State of Colorado. This is normally the same as the facility address. However, a Colorado post office box number is acceptable.
- Item 4.** Provide the name, daytime telephone number, fax number, and email address for the person at the applicant's facility who should be the management contact concerning the application.
- Item 5.** Indicate the physical address at which the radioactive materials will be stored and used. If this is the same as the applicant's mailing address indicate "SAME". However, a post office box number is **NOT** acceptable as a facility address in Item 5. If the applicant desires authorization for multiple storage and use locations, then attach separate sheets listing the physical address for each storage location.
- Item 6.** Provide the name, daytime telephone number, fax number, address, and email address for the person at the applicant's facility who should be the billing contact concerning the application.
- Item 7.** Designate the individual to be the Radiation Safety Officer (RSO). Please ensure that the management and the designated individual are familiar with the specific duties for the RSO that have been established in Section 7.7 of the Regulations.
- Item 8.** Designate one or more individuals to serve as the alternate Radiation Safety Officer. Provide a copy of the RSO's signed agreement to accept responsibilities in accordance with the requirements of Part 7.7.2 of the Regulations.
- Item 9.** Check to the left of each applicable item listed in Item 9 for which authorization for use is to be provided on the license.
- Item 10.** Attach a diagram for each facility identified in Item 5. The diagram must be 8 1/2" x 11", or folded to that size. The diagram can be hand drawn and need not be drawn to scale. The diagram must be sufficiently detailed to give a clear picture of your facility in relation to radioactive material storage or use. The diagram must identify the following items:
- A. radioactive material storage and use locations,
 - B. shielding around the storage/use area,
 - C. how adjacent areas are used, and
 - D. the areas near radioactive material storage and use locations where a member of the public could have unescorted access.

Item 11. Attach survey data and/or calculations to demonstrate compliance with dose limits for members of the public specified in Section 4.14 of the Regulations. Members of the public must not receive a dose greater than 2 millirem in any one hour or 100 millirem in a year in an unrestricted area. If radioactive materials may be released into the sewer or into gaseous effluents, provide calculations to demonstrate that the effluent levels are within the limits specified in Part 4, Tables II and III, and the constraint levels specified in Section 4.5.4.

Item 12. Your list of radioactive sources for reference and/or calibration should include those that may be possessed under the provisions of Section 7.19 of the Regulations. Please note that sources authorized by 7.19 may not be listed specifically on your license.

Items 13 through 16.

Please review the requirements for individual training and experience as established in Part 7, Appendix 7.A through Appendix 7.M. If you are relying on previous radioactive materials license authorization to fulfill training and experience requirements, please provide a copy of the complete radioactive materials license that was in effect on or after October 25, 2005 that specifically shows the previously approved authorizations for the individual(s).

Item 17. Provide a copy of your written procedures which will be implemented to perform the specific activities identified in Item 17. These written procedures must be sufficiently detailed to allow a reasonably trained individual to understand and complete required tasks and to allow the Department to evaluate the overall adequacy of the radioactive materials program. Additional guidance for other medical uses of radioactive material can be found on the NRC's website at:
<http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

Please Note: For Y-90 microsphere uses an Authorized Medical Physicists (AMP) authorized on the license is required to perform or directly supervise and review the pre and post vial/delivery system dose measurements used in calculating the administered dose to the patient. Additionally, the calculations and preparation of the dose, or the direct supervision and subsequent review of these activities, is also required by the AMP. This must be reflected in your submitted procedures.

Item 18. Please note Sections 7.31, 7.35, and 7.57.1 of the Regulations for specific requirements on the detection capabilities of your survey instruments.

Commitments C.1 through C.7 reflect requirements from the State of Colorado *Rules and Regulations Pertaining to Radiation Control* which apply to the medical use of radioactive materials. All applicable requirements of the Regulations have not been specifically addressed or incorporated into the application. The applicant must be thoroughly familiar with the requirements of the Regulations, the license, and the applicant's procedures established to fulfill regulatory requirements. Many of the commitments require that written procedures and/or other documents be maintained

by the licensee. Department inspectors will review required records, written procedures, and documentation of worker training and experience during site inspections.

Requesting Alternative Authorization

The applicant may request authorization to conduct activities not specifically provided for in this application. The applicant may also request authorization to conduct activities by alternate methods. To do so the licensee must submit written procedures and appropriate supporting documentation.

CERTIFICATE:

The individuals signing the application must have the authority to make commitments on behalf of the applicant. A signature indicates that the application and attachments contain true and correct information and that the applicant will abide by the commitments identified in the application and the State of Colorado *Rules and Regulations Pertaining to Radiation Control*.

The application is to be signed by both a management representative and the designated Radiation Safety Officer. The designated Radiation Safety Officer (RSO), must agree in writing to be responsible for implementing the radiation safety program. The licensee, through the RSO, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements.

A single copy of your completed application and all attachment should be e-mailed to CDPHE_hmradmat@state.co.us and the fee payment (and the application and attachments, if they cannot be submitted electronically) mailed to the Colorado Department of Public Health and Environment, Radiation Management Program, HMWMD-B2, 4300 Cherry Creek Drive South, Denver, Colorado 80246-1530. A copy of these documents must be retained by the applicant.

If you have specific questions, Ms. Cheri Hall, Licensing Lead, may be reached by phone at 303-692-3444, by fax at 303-691-7841, or by email at cheri.hall@state.co.us.

The Department's licensing staff are also available to answer questions and can meet with you prior to the submission of a license application to discuss any specific issues you may have regarding the licensing process, regulatory requirements, and the information to be provided with the application.

In some cases, a Department inspector may conduct a pre-licensing inspection at your facility to assist our staff in the preparation of the radioactive materials license.