



INSTRUCTIONS FOR PREPARATION OF APPLICATION FOR RADIOACTIVE MATERIAL LICENSE

An applicant for a new Radioactive Material License or for renewal of an existing Colorado Radioactive Material License must complete Form OR-RH-12 in detail. The applicant must cover the entire radioisotope program with one application. However, separate applications must be submitted for medical teletherapy and gamma irradiators. Supplemental sheets may be appended when necessary to provide complete information.

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.

An application fee as specified in Part 12 of the State of Colorado *Rules and Regulations Pertaining to Radiation Control* must accompany each application for new license or amendment request. Except for licenses subject to full cost, no application for a new license, or for the reinstatement of an expired license will be accepted for processing prior to payment of the full amount specified in Part 12 of the Regulations. If you have any questions concerning fees please call the Department at (303) 692-3300 prior to submitting your application.

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 State of Colorado Rules and Regulations Pertaining to Radiation Control (the Regulations). These references are identified by an "RH" number. For example: RH 4.6 references Part 4, Section 4.6, Occupational Dose Limits for Adults. All "RH numbers" reference the Regulations. The Regulations can be downloaded from: <https://www.colorado.gov/pacific/cdphe/radregs>

The submission of an incomplete application will often delay the issuance of the license because of the correspondence necessary to obtain information requested on the application. Pursuant to RH 12.4.1.5 of the Regulations, the Department will 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.

- Item 1.** Indicate whether the application is for a new license or the renewal of an existing license. For renewals or amendments, provide the license number and expiration date for your current 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 corporate name of the company.
- Item 3.** Indicate the applicant's current radioactive materials license number, if the application is for a renewal or amendment.
- Item 4.** Indicate the applicant's mailing address. A post office box address is acceptable.
- Item 5.** Provide the name, daytime telephone number, telefax number, and e-mail address for the person at the applicant's facility who should be contacted if there are questions regarding the application. This individual should be the designated Radiation Safety Officer for most applications. If you wish to receive informational notices via e-mail, so indicate.
- Item 6.** Name of person designated as Radiation Safety Officer. If the application is an amendment to change the radiation safety officer, it must be signed by someone other than the proposed Radiation Safety Officer. If the application is for multiple facility locations, identify the name of the individual to be designated as the on-site RSO for each location.

The individual designated as the RSO has the responsibility for assuring the implementation of the radiation safety program. This individual also provides assistance to other radiation workers when needed to assure radiation safety. For these reasons, the RSO is typically an individual who has more extensive training and experience than other authorized users to be listed on the license.

The documentation of training and experience provided for each RSO must clearly demonstrate that the individual has successfully completed formal training in the fundamentals of radiation and radiation safety and have had experience in the use/handling of radioactive material. The duration and content of formal training must be commensurate with the complexity of the radioactive materials program, radiation hazards associated with authorized activities, and the radiation detection/measurement equipment to be operated.

Attach a description of the Radiation Safety Officer's duties and authorities.

Submit evidence that the individual designated as Radiation Safety Officer has had training and experience appropriate to the types of radioactive materials, activities, and uses identified in this application. The documentation of training and experience provided for each RSO must clearly demonstrate that these individuals have successfully completed formal training in the fundamentals of radiation and radiation safety and have had experience in the use/handling of radioactive material.

Training considered essential to the safe use of radioactive materials includes:

- A. Principles and practices of radiation protection.
- B. Radioactivity measurement standardization and monitoring techniques and instruments.
- C. Mathematics and calculations basic to the use and measurement of radioactivity.
- D. Biological effects of radiation.

For each training program, include:

- Subject and course outline
- Type of training (e.g., formal course, on-the-job, or seminar)
- Hours in training (specifically related to the use of radioactive materials.)
- Dates and location of training
- Organization providing the training
- A description of the trainer's qualifications
- College or university attended, major, and degrees awarded
- Attach copies of any relative certificates and/or board certifications. Physicians should include a copy of their Colorado Medical License.

To demonstrate experience with use of radioactive materials, include:

- Where experience was gained
- Dates of experience (beginning and end dates)
- Isotopes used
- Activity
- Chemical/Physical form
- Types of use

- Item 7.** 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 8.** Provide the name, daytime telephone number, fax number, and email address for the person at the applicant's facility who should be the billing contact concerning the application.
- Item 9.** Indicate the physical address from where licensed activities will be conducted. This address would include the location where radioactive materials will be received, possessed, processed, stored or used. If this address is the same as the applicant's mailing address you may simply indicate "SAME" in the space provided. However, a post office box number is NOT acceptable as a facility address in Item 9. If the applicant desires authorization for multiple locations, then attach separate sheets listing the physical address for each location.

If no radioactive materials will be received, possessed, processed, or stored at the applicant's facility, then initial in the space provided.

- Item 10.** List by element and mass number each radioisotope desired, such as "Carbon 14, "Cobalt 60, "Americium 241:Be, etc. See Item 10 in the example. Attach additional pages if necessary.

For **MEDICAL** applicants groups of radioactive materials may be requested by reference to specific sections of the Regulations. For example: the use of radiopharmaceuticals for imaging and localizations studies are specified in RH.7.32 of the Regulations. See Item 10.F. in the example.

Item 11. List the chemical and/or physical form for each radioisotope identified in Item 10. If more than one chemical and/or physical form of a particular radioisotope is desired, a separate possession limit should be stated for each form. See Items 11.C. and 11.D. in the example. If the radioactive material is to be obtained as a sealed source, specify the physical form as "sealed source" and include the manufacturer and model number for that sealed source. See Item 11.A. in the example. Attach additional pages if necessary.

Item 12. Specify the maximum amount of activity for each isotope listed in Item 10. If the radioactive source is a sealed source, "foil, etc, then also state the number of sources the applicant desires to possess at any one time. See Item 12 in the example. Attach additional pages if necessary.

Example

10. Radioactive Material Element and Mass	11. Chemical/Physical Form	12. Maximum Activity
A. Americium 241:Be	A. Sealed Source, Troxler Dwq. A-100337 A	A. 2 sources, 11.1 GBq (300 millicuries) each
B. Cobalt 60	B. Sealed Source, J.L.Shepherd model 7810	B. 18.5 GBq (550 millicuries)
C. Iodine 131	C. Iodide	C. 370 MBq (10 millicuries)
D. Iodine 131	D. Iodinated Serum Albumin	D. 37 KBq (1 microcurie)
E. Nickel 63	E. Foil, Safety Light model LAB-784	E. 3.7 GBq (100 millicuries) Per source. Total sources not to exceed five (5)
F. Radioactive materials authorized in RH 7.32 of the Regulations.	F. Any radiopharmaceutical, generator, or reagent kit listed in RH 7.32 of Part 7 of the Regulations.	F. 370 GBq (10 Ci)

Item 13. State the use of each radioactive isotope and chemical/physical form specified in Item 10 and Item 11. Attach additional pages if necessary.

Purpose for Radioactive Material:

- A. Used in a Troxler model 3241 series asphalt content gauge for asphalt content tests.
- B. Used in a J.L. Shepherd model 28 calibrator for the calibration of survey instruments.
- C. Used for In-Vitro analysis of rat thyroid tissue.
- D. Used in laboratory studies of rats.
- E. Used in a Philips Electronics model 134 detector cell for gas chromatography.
- F. Used in any procedure categorized in RH 7.32 of Part 7 of the Regulations.

Item 14. The "Individual Users" are the persons who will use unsupervised, or supervise the use of radioisotopes. If the application is for "human use", the individual user must be licensed by the State of Colorado to dispense drugs in the practice of medicine and meet the requirements of Part 7 of the Regulations regarding formal training and experience. The training and experience of each individual must be adequate and applicable to that individual's assigned duties involving exposure to radiation or handling of radioactive materials.

Submit evidence that the individual users have had training appropriate to the types of radioactive materials, activities, and uses identified in this application. If more than one individual is named in Item 14, clearly key the name of each individual to his/her training. Attach copies of any certifications awarded to each individual.

Topics considered essential to the safe use of radioactive materials include:

- A. Principles and practices of radiation protection.
- B. Radioactivity measurement standardization and monitoring techniques and instruments.
- C. Mathematics and calculations basic to the use and measurement of radioactivity.
- D. Biological effects of radiation.

List the experience with radioactive materials for the individual user of radioactive materials. If more than one individual is named in Item 14, clearly key the name of each individual to his/her experience.

For each training program, include:

Subject and course outline

Type of training (e.g., formal course, on-the-job, or seminar)

Hours in training (specifically related to the use of radioactive materials.

Dates and location of training

Organization providing the training

A description of the trainer's qualifications

College or university attended, major, and degrees awarded

Attach copies of any relative certificates and/or board certifications.

Physicians should include a copy of their Colorado Medical License.

To demonstrate experience with use of radioactive materials, include:

Where experience was gained

Dates of experience (beginning and end dates)

Isotopes used

Activity

Chemical/Physical form

Types of use

For **MEDICAL** applications, individuals may also have to submit board certification or a signed and dated Form OR-RH-13 to demonstrate clinical training and experience. Users at medical institutions, as defined in RH 7.2, are designated by the institution's Radiation Safety Committee.

Item 15. Identify the radiation detection instruments and probes that will be used in conjunction with your radioactive materials program. The instrument and probe must be capable of detecting the emissions from the specific radioactive materials for which the survey is being conducted. Also, the sensitivity and efficiency of the instrument must be appropriate for the type of use. Describe how the instruments will be used (area surveys, contamination surveys, wipe counting, etc).

Item 16. Submit a copy of your calibration procedures.

- A. The calibration of a survey instrument must be made with an appropriate radioactive source, which is traceable to the National Institute for Standards and Technology (NIST). Specify the manufacturer, model number, radionuclide, maximum activity of each source and the total number of sources of each type. If a specific source is to be used within a device or as part of a piece of

equipment also provide the manufacturer and model number of the device or equipment.

- B. The individual performing the calibration must have at least 40 hours of formal course work and 1 week of on-the-job training. The topics of the formal training are outlined in Item 14 of these instructions. The on-the-job training must include hands-on experience in calibrating instruments.
- C. If the instrument cannot be calibrated to within 20% of the actual activity, the instrument must be returned to manufacturer for repair or a graph or table of correction factors must be attached to the instrument.
- D. If a commercial service is to be used, the company must be licensed to provide that service. Submit the company's name, address, and license number.

Item 17. The supplier of film badges, TLD's or optically stimulated luminescence dosimeters (OSL) must be approved by the National Voluntary Laboratory Accreditation Program (NVLAP). The frequency of exchange for film badges must not exceed 1 month, and should comply with the manufacturer's specifications for TLD's and OLS's. If an audible radiation dosimeter or pocket dosimeter is used then specify the manufacturer and model of the dosimeter used. Also specify the frequency and procedures for the calibration of these dosimeters.

Item 18. Facilities and Handling Equipment:

- A. Specify the types of equipment that will be used in conjunction with radioactive materials. Examples would include remote handling devices, fume hoods, lead shields, storage containers, shipping containers, lead aprons, and other safety equipment.

606B. The sketch of your facility must be sufficiently detailed to give a clear picture of your facility in relation to radioactive material usage.

Clearly identify the locations or areas where:

- 1) radioactive materials are used and stored;
- 2) special equipment and shielding are used;
- 3) area surveys and wipes will be conducted;
- 4) fume hoods and exhaust vents are used;
- 5) fume hoods and exhaust vents are discharged to the outside air;
- 6) radioactive materials warning signs and notices are posted;
- 7) non-radiation workers or the general public will have access.

- B. Attach calculations and/or survey results to demonstrate compliance with dose limits for members of the public at all storage and use locations. (See RH 4.14 and RH 4.15) Include calculations of average air and water effluent levels for radionuclides, if applicable. Provide written procedures for complying with public dose limits while performing services for other licensees.

Item 19. The description of your radiation protection program must cover the entire scope of your radioactive materials usage. These procedures should describe in detail how the applicant will perform activities. Attach written operating procedures for each activity that is appropriate.

- A. Procedures to keep personnel exposures ALARA. Submit a description of the annual ALARA review or audit.

B. Procedures for the safe use of radioactive materials

- 1) procedures for using radiation detection equipment, and

radionuclide/isotope identification

C. Personnel monitoring procedures

D. Emergency procedures

- E. Procedures to ensure adequate security of radioactive materials
- F. Procedures for storage of radioactive materials
- G. Procedures for contamination control
- H. Procedures for receiving and shipping radioactive materials. All shipments of radioactive materials must meet the requirements of the U.S. Department of Transportation. Include procedures for surveying packages, receipt of materials after business hours, and for handling contaminated or leaking packages.
- I. Procedures for leak testing sealed sources and describe actions to be taken if a sealed source is found to be leaking. The test must be capable of detecting 0.005 microcurie of removable activity.
- J. If radioactive materials will be used in normal form, submit:
 - 1) Procedures of conducting area surveys and wipes. Describe the lowest level of contamination detected, and specify the levels of contamination, which will require clean-up.
 - 2) Procedures for the clean-up of spills involving radioactive materials.
 - 3) If appropriate, include:
 - i. Air sampling.
 - ii. Water / soil sampling
 - iii. Sampling bulk liquids or solids for radionuclides
 - 4) If material is volatile, calculate or demonstrate compliance with NESHAPS constraint limit of 0.1 mSv (10 millirem) per year.
- K. If a commercial service is employed to determine the level of contamination on wipes from leak tests or area surveys, then specify the name of the company, address, and license number. NOTE: Companies providing this service must have a Radioactive Materials License that authorizes this service.
- L. If the licensee will determine the level of contamination on wipes, then submit detailed procedures for counting wipes and a description of the equipment used.
- M. If the licensed activities involve operations, which utilize, at any one time, more than 100 millicuries of Hydrogen 3 in a non-contained form, other than metallic foil, then submit procedures for performing bioassays and evaluating the test results.
- N. If the licensed activities involve operations that utilize, at any one time, more than 50 millicuries of I-125 and/or I-131 or unvented laboratory operations involving 10 millicuries of I-125 and/or I-131, then submit procedures for performing bioassays and evaluating the burden to the thyroid.
- O. If the licensed activities involve the transportation of radioactive materials, then submit transportation procedures. The transportation of radioactive materials must satisfy the requirements of the U.S. Department of Transportation and other agencies having jurisdiction. **Your procedures must include the prompt notification of this Division in the event of an accident involving radioactive materials.**
- P. If the licensee will provide training to its personnel involving the use of radioactive materials, then submit an outline of the course, the numbers of hours of instruction given to personnel, frequency of training, and the qualifications of the person who will give the training. Also describe the duties of the individual receiving this training. If separate classes are given to different types of employees, then describe each program.

- Q. If the licensed activities involve the **Medical Use** of radioactive materials, then:
- 1) Describe your Radiation Safety Committee, including its members, the frequency of meetings, and its responsibilities.
 - 2) Submit procedures for the safe use of radiopharmaceuticals
 - 3) Submit procedures for the control of radioactive aerosols and gases.
 - 4) Submit procedures for safety during nuclear medicine therapy.
 - 5) Submit procedures for the calibration of dose calibrators.
 - 6) Submit procedures for the control of molybdenum 99 concentrations.
 - 7) Submit procedures for the calibration of imaging equipment.

R. Obtaining waste disposal permits

Item 20. Submit procedures for the disposal of sealed sources, radioactive waste, and contaminated items. Also estimate the amount of waste expected to be generated each year.

A. If radioactive materials will be stored for decay, then the waste **MUST** be stored a minimum of 10 half-lives. All waste **MUST** be surveyed prior to disposal and the waste **MUST** be indistinguishable from background. The survey must be conducted with all shielding removed, in a low background area with an appropriate instrument. In addition to the survey, all radioactive labels must be removed or obliterated.

If radioactive materials will be disposed of via the sewer system, then submit your procedures and calculations which demonstrate that the release limits specified in RH 4.35 are not exceeded.

B. If a commercial waste disposal service is employed for services other than transportation (e.g., surveys, labeling, plackarding), then specify the name of the company, address, and license number. Also describe the services provided. **NOTE:** Companies providing this service must have a Radioactive Materials License that authorizes this service.

RADIUM: The licensee must furnish evidence of the licensee's ability to lawfully dispose of the Radium source(s) to be possessed by the licensee. The evidence must include the name and address of the company/licensee to which the source(s) would be sent for disposal during the period of time this license is valid. The evidence must also include the ability of the receiving company/licensee to receive such source(s). The ability to dispose of the Radium source(s), and documents supporting that ability, must be maintained by the licensee until lawful disposal of the Radium source(s) has been completed.

NOTE: Beginning January 1, 1993 greater than Class C quantities of radioactive waste are not acceptable at the available low-level waste site. Until the Department of Energy develops a waste site for greater than Class C wastes you will most likely have to store such sources at your location unless such sources can be returned to the vender. Refer to Appendix E of Part 4 for the classification of waste.

Item 21. Demonstrate that the requirements of RH 3.9.5 have been satisfied. The requirements for financial assurance are based on the isotope, physical form, and activity of licensed materials.

Certificate. The certificate must be signed and dated. The individual signing the application for an institution must hold a position of responsibility for that institution.

The designated Radiation Safety Officer must also sign and date the application.

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.