

Regulatory Information for General Licensees

The complete State of Colorado *Rules And Regulations Pertaining To Radiation Control* can be viewed and downloaded from the web at:

<http://www.colorado.gov/cdphe>

The following excerpts have been identified to provide you with an overview of some of the applicable regulatory requirements.

PART 1: GENERAL PROVISIONS

- 1.2 "Licensee" means any person who is licensed by the Department in accordance with these regulations and the Act. "Licensee" also means any person who is responsible for decommissioning by being registered with the Department, being subject to a record of possession of a radiation source or device under general license (for example, pursuant to 3.6.4.3(13)), or being otherwise legally obligated to conduct decommissioning activities in accordance with these regulations and the Act.
- 1.6 Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in these regulations.
- 1.7.1 Each licensee and registrant shall afford the Department at all reasonable times opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.
- 1.7.2 Each licensee and registrant shall make available to the Department for inspection, at all reasonable times, records maintained pursuant to these regulations.

PART 3: LICENSING OF RADIOACTIVE MATERIAL

- 3.4.1 A general license is provided by regulation and grants authority to a person for certain activities involving radioactive material. A general license is effective without the filing of an application with the Department or the issuance of a licensing document to a particular person. However, registration or filing of a certificate with the Department may be required by the particular general license. The general licensee is subject to all other applicable portions of these regulations and any limitations of the general license.

Section 3.6 of the Regulations contains specific requirements pertaining to generally licensed radioactive materials. These include: static elimination devices; ion generating tubes; certain measuring, gauging or controlling devices; and luminous safety devices.

- 3.6.4.3 Any person who owns, receives, acquires, possesses, uses, owns, or transfers radioactive material in a device pursuant to the general license in 3.6.4.1:
- (1) Shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;
 - (2) Shall assure that the device is tested for leakage of radioactive material and proper operation of the "on-off" mechanism and indicator, if any, at no longer than 6-month intervals or at such other intervals as are specified in the label, however;
 - (a) Devices containing only krypton need not be tested for leakage of radioactive material; and
 - (b) Devices containing only tritium or not more than 3.7 MBq (100 μ Ci) of other beta- and/or gamma-emitting material or 0.37 MBq (10 μ Ci) of alpha-emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;
 - (3) Shall assure that other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed:
 - (a) In accordance with the instructions provided by the labels; or
 - (b) By a person holding an applicable specific license from the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform such activities;
 - (4) Shall maintain records showing compliance with the requirements of 3.6.4.3(2) and 3.6.4.3(3). The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by 3.6.4.3(2) shall be maintained for 1 year after the next required leak test is performed or until the sealed source is transferred or disposed of. Records of tests of the "on-off" mechanism and indicator required by 3.6.4.3(2) shall be maintained for 1 year after the next required test of the "on-off" mechanism and indicator is performed or until the sealed source is transferred or disposed of. Records which are required by 3.6.4.3(3) shall be maintained for a period of 2 years from the date of the recorded event or until the device is transferred or disposed of;

- (5) Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the "on-off" mechanism or indicator, or upon the detection of 185 Bq (0.005 μ Ci) or more removable radioactive material, shall immediately suspend operation of the device, and
- (a) The device shall not be operated until it has been repaired by the manufacturer or other person holding an applicable specific license from the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to repair such devices;
 - (b) The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device; and
 - (c) Within 30 days, the general licensee shall furnish to the Department a report containing a brief description of the event and the remedial action taken;
 - (d) And, in the case of detection of 185 Bq (0.005 microcurie) or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, the general licensee shall furnish to the Director of the Hazardous Materials And Waste Management Division, within 30 days, a plan for ensuring that the premises and environs are acceptable for unrestricted use. Under these circumstances, the criteria set out in 4.61.2, "Radiological Criteria For Unrestricted Use," may be applicable, as determined by the division on a case by case basis;
- (6) Shall not abandon the device containing radioactive material;
- (7) Shall not export the device except in accordance with 10 CFR Part 110 (January 1, 2004) and shall obtain written approval from the U.S. Nuclear Regulatory Commission before transferring the device to any other specific licensee not specifically identified in 3.6.4.3(8);
- (8) Except as provided in 3.6.4.3(9), shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State whose specific license authorizes receipt of the device and within 30 days after transfer of a device to a specific licensee shall furnish to the Department a report containing:
- (a) Identification of the device by manufacturer's (or initial transferor's) name, model number and serial number;
 - (b) The name, address and license number of the person receiving the device;
 - (c) The date of the transfer;

- (d) The identity of the radionuclide(s) present and activity present, by assay or calculation;
- (9) Shall transfer the device to another general licensee only:
- (a) Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this regulation and any safety documents identified in the label on the device and within 30 days of the transfer, report to the Department the manufacturer's (or initial transferor's) name and model number and serial number of device transferred, the identity of the radionuclide(s) present and assayed or calculated activity present, the transferee's name and mailing address for the location of use, and the name title, and phone number of the responsible individual identified by the transferee in accordance with 3.6.4.3(12) to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or
 - (b) Where the device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee; and
- (10) Shall comply with the provisions of 4.51 and 4.52 for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of Parts 4 and 10;
- (11) Shall respond to written requests from the Department to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the director of the Hazardous Materials And Waste Management Division a written justification for the request;
- (12) Shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements; this appointment does not relieve the general licensee of any of its responsibility in this regard;
- (13) Shall register each device annually in accordance with 3.6.4.3(13)(a) and 3.6.4.3(13)(b), and shall pay the fee required by part 12, if in possession of a device containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, or 37 MBq (1 mCi) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label;
- (a) Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Department. The registration information must be

submitted to the Department within 30 days of the date of the request for registration or as otherwise indicated in the request.

- (b) In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Department:
 - (i) Name and mailing address of the general licensee;
 - (ii) Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label);
 - (iii) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under 3.6.4.3(12);
 - (iv) Address or location at which the device(s) are used and/or stored; for portable devices, the address of the primary place of storage;
 - (v) Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information; and
 - (vi) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.
 - (c) A general licensee holding devices meeting the criteria of 3.6.4.3(13) is subject to the bankruptcy notification requirement in 3.15.5.
 - (d) Persons generally licensed by an Agreement State with respect to devices meeting the criteria in paragraph 3.6.4.3(13) are not subject to U.S. Nuclear Regulatory Commission registration requirements if the devices are used in areas subject to NRC jurisdiction for a period less than 180 days in any calendar year. The Commission will not request registration information from such licensees.
- (14) Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the director of the hazardous materials and waste management division within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage.
- (15) May not hold a device that is not in use for longer than 2 years. If a device with shutters is not being used, the shutter must be locked in the closed position. The testing required by 3.6.4.3(2) need not be performed during the period of storage only. However, when a device is put back into service or transferred to another person, and has not been tested within the required test interval, the device must be tested for leakage

before use or transfer and the shutter tested before use. A device kept in standby for future use is excluded from the two-year time limit if the general licensee performs quarterly physical inventories of the device while the device is in standby.

PART 12: FEES FOR MATERIALS LICENSES

- 12.5.1 Persons who hold general licenses under the following categories shall pay an annual fee:
 - 12.5.1.3 Measuring, gauging and controlling devices under RH 3.6.4; and,
 - 12.5.1.4 *In vitro* licenses under RH 3.6.9.
- 12.5.3 Fees for general licenses are listed in Appendix A of this Part and shall be payable every July 1, for as long as the license remains in effect.
- 12.5.4 Fees for inspection of licenses, authorized under RH 3.5.5 and 3.6, that are based on the full cost of the inspection are payable upon notification by the Department.

CATEGORY 17 - GENERAL LICENSESⁱ

17.A Source Material, gauges and other similar devices pursuant to RH 12.5.11 through 12.5.1.1.3.

Annual Fee	\$100
Inspection	Full Cost

ⁱ Fees are for each license at each facility. Fees for general licenses are annual fees, and are due July 1 each year. Non-routine inspections of general licensees related to 1) exposures to individuals; or 2) release of radioactive materials in excess of limits established in Part 4 of these regulations.