



ADMINISTRATIVE RULES OF MONTANA



37.14.512 GENERAL LICENSES: RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL

- (1) A general license is hereby issued to transfer, receive, acquire, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the US nuclear regulatory commission for use pursuant to 10 CFR Part 31, section 31.3. This general license is subject to the provisions of ARM 37.14.107 , 37.14.108 , 37.14.115 , 37.14.116 , 37.14.506 (1) (b) , 37.14.526 , 37.14.547 , 37.14.550 , 37.14.552 , and Title 37, chapter 14, subchapters 7 and 17.
 - (a) Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device.
 - (b) Devices designed for ionization of air which contain as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device or a total of not more than 50 millicuries of hydrogen-3 (tritium) per device.
- (4)
 - (a) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to receive, acquire, possess, use, or transfer in accordance with the provisions of (b) through (d) below, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.
 - (b) The general license in (a) above applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the department pursuant to ARM 37.14.542 (4) or in accordance with the specifications contained in a specific license issued by the US nuclear regulatory commission, an agreement state or a licensing state, which authorizes distribution of devices to persons generally licensed by the US nuclear regulatory commission, an agreement state or a licensing state.
 - (c) Any person who receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in (a) above:

- (i) 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;
- (ii) 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 100 microcuries of other beta and/or gamma emitting material or 10 microcuries 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;
- (iii) shall assure that the tests required by (ii) above and other testing, installation, servicing, and removal from installation involving the radioactive materials, 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 US nuclear regulatory commission, an agreement state or a licensing state to perform such activities;
- (iv) shall maintain records showing compliance with the requirements of (ii) and (iii) above. 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, installing, servicing, and removing from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by (ii) above 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 (ii) above 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 (iii) above 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;
- (v) 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 0.005 microcurie or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the department, the US nuclear regulatory commission, an agreement state or a licensing state to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the department a report containing a brief description of the event and the remedial action taken;
- (vi) shall not abandon the device containing radioactive material;

- (vii) except as provided in (viii) below, shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the department, the US nuclear regulatory commission, an agreement state, or a licensing state whose specific license authorizes him to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the department a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;
- (viii) shall transfer the device to another general licensee:
 - (A) where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this rule 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 name and model number of device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the department and the transferee; or
 - (B) where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee; and
- (ix) shall comply with the provisions of ARM 37.14.751 and 37.14.755 , for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of ARM Title 37, chapter 14, subchapters 7 and 17.
- (d) The general license in (a) above does not authorize the manufacture of devices containing radioactive material.
- (e) The general license provided in (a) above is subject to the provisions of ARM 37.14.107 , 37.14.108 , 37.14.115 , 37.14.116 and 37.14.526 , 37.14.547 , 37.14.550 , and 37.14.552 .
- (5)
 - (a) A general license is hereby issued to receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:
 - (i) each device contains not more than 10 curies of tritium or 300 millicuries of promethium-147; and
 - (ii) each device has been manufactured, assembled or imported in accordance with a specific license issued by the US nuclear regulatory commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the department or any agreement state to the manufacturer or assembler of such device.
 - (b) Persons who receive, acquire, possess, or use luminous safety devices pursuant to the general license in (a) above are exempt from the requirements of ARM Title 37, chapter 17, subchapters 7 and 17, except that they shall comply with the provisions of ARM 37.14.751 and 37.14.755 .
 - (c) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

- (d) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.
- (e) This general license is subject to the provisions of ARM 37.14.107 , 37.14.108 , 37.14.115 , 37.14.116 , 37.14.526 , 37.14.547 , 37.14.550 , and 37.14.552 .

(6) A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this subchapter, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

(7)

- (a) A general license is hereby issued to those persons listed below to receive, acquire, possess, use, and transfer, in accordance with the provisions of (d) and (e) below, americium-241 in the form of calibration or reference sources:
 - (i) any person who holds a specific license issued by the department which authorizes him to receive, possess, use, and transfer radioactive material; and
 - (ii) any person who holds a specific license issued by the US nuclear regulatory commission which authorizes him to receive, possess, use, and transfer special nuclear material.
- (b) A general license is hereby issued to receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of (d) and (e) below to any person who holds a specific license issued by the department which authorizes him to receive, possess, use, and transfer radioactive material.
- (c) A general license is hereby issued to receive, possess, use, and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of (d) and (e) below to any person who holds a specific license issued by the department which authorizes him to receive, possess, use, and transfer radioactive material.
- (d) The general licenses in (a) , (b) and (c) above apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the US nuclear regulatory commission or which have been manufactured in accordance with the specification contained in a specific license issued to the manufacturer by the department, any agreement state or licensing state.
- (e) The general licenses provided in (a) , (b) , and (c) above are subject to the provisions of ARM 37.14.107 , 37.14.108 , 37.14.115 , 37.14.116 , 37.14.526 , 37.14.547 , 37.14.550 , 37.14.552 , and Title 37, chapter 14, subchapters 7 and 17. In addition, persons who receive, acquire, possess, use, or transfer 1 or more calibration or reference sources pursuant to these general licenses:

(i) shall not possess at any 1 time, at any 1 location of storage or use, more than 5 microcuries of americium-241, 5 microcuries of plutonium, or 5 microcuries of radium-226 in such sources;

(ii) shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes 1 of the following statements, as appropriate, or a substantially similar statement which contains the information called for in 1 of the following statements, as appropriate:

(A) The receipt, possession, use and transfer of this source, Model , Serial No. , are subject to a general license and the regulations of the US nuclear regulatory commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION--RADIOACTIVE MATERIAL-- THIS SOURCE CONTAINS _____

(AMERICIUM-241 or PLUTONIUM--show only the name of the appropriate material.)

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer of importer

(B) The receipt, possession, use and transfer of this source, Model _____,
Serial No. _____, are subject to a general license and the regulations of any licensing
state. Do not remove this label. CAUTION--RADIOACTIVE MATERIAL--THIS SOURCE
CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or importer

(iii) shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the department, the US nuclear regulatory commission, an agreement state or a licensing state to receive the source;

(iv) shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

(v) shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(f) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

(8)

(a) A general license is hereby issued to any physician to receive, possess, transfer, or use radioactive material set forth below for the stated diagnostic uses, provided, however, that the use is in accordance with the provision of (b) , (c) and (d) below, the radioactive material

is in the form of capsules, disposable syringes, or other prepackaged individual doses; and the radioactive material has been manufactured in accordance with a specific license issued by the department pursuant to ARM

- (i) iodine-131 as sodium iodide (Na^{131}I) for measurement of thyroid uptake;
 - (ii) iodine-131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;
 - (iii) iodine-125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;
 - (iv) (reserved)
 - (v) cobalt-58 for the measurement of intestinal absorption of cyanocobalamin ;
 - (vi) cobalt-60 for the measurement of intestinal absorption of cyanocobalamin ; and
 - (vii) chromium-51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time.
- (b) No physician shall receive, possess, use, or transfer radioactive material pursuant to the general license established by (a) above until he has filed department form MRH-10, "Certificate--Medical Use of Radioactive Material Under General License" with the department and received from the department a validated copy of the department form MRH-10 with certification number assigned. The generally licensed physician shall furnish on department form MRH-10 the following information and such other information as may be required by that form:
- (i) name and address of the generally licensed physician;
 - (ii) a statement that the generally licensed physician is a duly licensed physician (authorized to dispense drugs) in the practice of medicine in Montana; and
 - (iii) a statement that the generally licensed physician has appropriate radiation measuring instruments to carry out the diagnostic procedures for which he proposes to use radioactive material under the general license of this (8) and that he is competent in the use of such instruments.
- (c) A physician who receives, possesses, or uses a pharmaceutical containing radioactive material pursuant to the general license established by (a) above shall comply with the following:
- (i) He shall not possess at any 1 time, pursuant to the general license in (a) above more than:
 - (A) 200 microcuries of iodine-131,
 - (B) 200 microcuries of iodine-125,
 - (C) 5 microcuries of cobalt-57,
 - (D) 5 microcuries of cobalt-58,

- (E) 5 microcuries of cobalt-60, and
- (F) 200 microcuries of chromium-51;
- (ii) he shall store the pharmaceutical in the original shipping container, or a container providing equivalent radiation protection until administered;
- (iii) he shall use the pharmaceutical only for the uses authorized by (a) above;
- (iv) he shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under 18 years of age; and
- (v) he shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the department, the US nuclear regulatory commission, any agreement state or licensing state, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.
- (d) The generally licensed physician possessing or using radioactive material under the general license of (a) above shall report in duplicate to the department, any changes in the information furnished by him in the "Certificate--Medical Use of Radioactive Material Under General License", department form MRH-10. The report shall be submitted within 30 days after the effective date of such change.
- (e) Any person using radioactive material pursuant to the general license of (a) above is exempt from the requirements of ARM Title 37, chapter 14, subchapters 7 and 17, with respect to the radioactive material covered by the general license.
- (9)
 - (a) A general license is hereby issued to any physician, clinical laboratory or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of (b) through (f) below, the following radioactive materials in prepackaged units:
 - (i) Iodine-125, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
 - (ii) Iodine-131, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
 - (iii) Carbon-14, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
 - (iv) Hydrogen-3 (tritium) , in units not exceeding 50 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
 - (v) Iron-59, in units not exceeding 20 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

- (vi) Cobalt-57, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
 - (vii) Selenium-75, in units not to exceed 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
 - (viii) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
- (b) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by (a) above until he has filed department form MRH-11, "Certificate--In Vitro Testing with Radioactive Material Under General License", with the department and received from the department a validated copy of department form MRH-11 with certification number assigned, or until he has been authorized pursuant to ARM 37.14.540 (3) (c) to use radioactive material under the general license in (9) . The physician, clinical laboratory or hospital shall furnish on department form MRH-11 the following information and such other information as may be required by that form:
- (i) name and address of the physician, clinical laboratory or hospital;
 - (ii) the location of use; and
 - (iii) a statement that the physician, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in (a) above and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.
- (c) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by (a) above shall comply with the following:
- (i) The general licensee shall not possess at any 1 time, pursuant to the general license in (a) above, at any 1 location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, and/or cobalt-57 in excess of 200 microcuries.
 - (ii) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.
 - (iii) The general licensee shall use the radioactive material only for the uses authorized by (a) above.
 - (iv) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the department, the US nuclear regulatory commission, any agreement state or licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.
 - (v) The general licensee shall dispose of the mock iodine-125 reference or calibration sources described in (a) (viii) above as required by ARM 37.14.740 .

(d) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to (a) above:

(i) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to ARM 37.14.542 (8) in accordance with the provisions of a specific license issued by the US nuclear regulatory commission, any agreement state or licensing state which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium) , iron-59, selenium-75, cobalt-57, or mock iodine-125 to persons generally licensed under (9) or its equivalent, and

(ii) unless 1 of the following statements, as appropriate, or a substantially similar statement which contains the information called for in 1 of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(A) This radioactive material shall be received, acquired, possessed, and used only by

physicians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests

not involving internal or external administration of the material, or the radiation therefrom, to

human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject

to the regulations and a general license of the US nuclear regulatory commission or of a state

with which the commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer

(B) This radioactive material shall be received, acquired, possessed, and used only by

physicians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests

not involving internal or external administration of the material, or the radiation therefrom,

to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject

to the regulations and a general license of a licensing state.

Name of manufacturer

- (e) The physician, clinical laboratory or hospital possessing or using radioactive material under the general license of (a) above shall report in writing to the department, any changes in the information furnished by him in the "Certificate--In Vitro Testing with Radioactive Material Under General License", department form MRH-11. The report shall be furnished within 30 days after the effective date of such change.
- (f) Any person using radioactive material pursuant to the general license of (a) above is exempt from the requirements of ARM Title 37, chapter 14, subchapters 7 and 17, with respect to radioactive material covered by that general license, except that such persons using the mock iodine-125 described in (a) (viii) above shall comply with the provisions of ARM 37.14.740 , 37.14.751 , and 37.14.755 .

(10)

- (a) A general license is hereby issued to receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the US nuclear regulatory commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the department or any agreement state to the manufacturer of such device.
- (b) Persons who receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in (a) above:
 - (i) shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the US nuclear regulatory commission or an agreement state to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of ARM 37.14.740 .
 - (ii) shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and
 - (iii) are exempt from the requirements of ARM Title 37, chapter 14, subchapters 7 and 17, except that such persons shall comply with the provisions of ARM 37.14.740 , 37.14.751 , and 37.14.755 .
- (c) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.
- (d) This general license is subject to the provisions of ARM 37.14.107 , 37.14.108 , 37.14.115 , 37.14.116 , 37.14.526 , 37.14.547 , 37.14.550 , and 37.14.552 .

Authorizing statute(s): Sec. 75-3-202, MCA

Implementing statute(s): Sec. 75-3-202, MCA

History: NEW, 1980 MAR p. 1069, Eff. 3/28/80; TRANS, from DHES, 1996 MAR p. 433; TRANS, from DEQ, 2000 MAR p. 189.