



ADMINISTRATIVE RULES OF MONTANA

37.14.542 SPECIFIC LICENSES: SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO MANUFACTURE, ASSEMBLE, REPAIR, OR DISTRIBUTE COMMODITIES, PRODUCTS, OR DEVICES WHICH CONTAIN RADIOACTIVE MATERIAL

(1)

- (a) In addition to the requirements set forth in ARM
 - (i) the applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and
 - (ii) the applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Schedule A of this subchapter, that reconcentrating of the radioactive material in concentrations exceeding those in Schedule A is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.
 - (b) Each person licensed under (1) shall file an annual report with the department which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to (1) during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within 30 days thereafter.
- (2) Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing by-product material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the US Nuclear Regulatory Commission, Washington, DC 20555.

- (a) An application for a specific license to distribute naturally-occurring and accelerator-produced radioactive materials (NARM) to persons exempted from this subchapter pursuant to ARM 37.14.506 (2) will be approved if:
 - (i) the radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;
 - (ii) the radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and
 - (iii) the applicant submits copies of prototype labels and brochures and the department approves such labels and brochures.
- (b) The license issued under (a) above is subject to the following conditions:
 - (i) No more than 10 exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of 1 or more of the exempt quantity provided the sum of the fractions shall not exceed unity.
 - (ii) Each exempt quantity shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to ARM 37.14.506 (2) . The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.
 - (iii) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:
 - (A) identifies the radionuclide and the quantity of radioactivity, and
 - (B) bears the words "Radioactive Material".
 - (iv) In addition to the labeling information required by (iii) above, the label affixed to the immediate container, or an accompanying brochure, shall:
 - (A) state that the contents are exempt from licensing state requirements,
 - (B) bear the words "Radioactive Material--Not for Human Use--Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited--Exempt Quantities should not be Combined", and
 - (C) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.
- (c) Each person licensed under (2) shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under ARM 37.14.506 (2) or the equivalent regulations of a licensing state, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the department. Each report shall cover the year ending June 20, and shall be filed within 30 days thereafter. If no

transfers of radioactive material have been made pursuant to (2) during the reporting period, the report shall so indicate.

- (3) An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under ARM 37.14.506 (3) (c) will be approved if the application satisfies requirements equivalent to those contained in 10 CFR Part 32, section 32.26.

(4)

- (a) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under ARM
- (i) the applicant satisfies the general requirements of ARM 37.14.521 ;
 - (ii) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:
 - (A) the device can be safely operated by persons not having training in radiological protection,
 - (B) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of 1 calendar quarter a dose in excess of 10% of the limits specified in the table in ARM 37.14.705 (1) , and
 - (C) under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external addition dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active

blood-forming organs; gonads; 15 rams

or lens of eye

Hands and forearms; feet and ankles;

localized areas of skin averaged 200 rams

over areas no larger than 1 square

centimeter

Other organs 50 rams

- (iii) each device bears a durable, legible, clearly visible label or labels approved by the department, which contain in a clearly identified and separate statement:
- (A) instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information) ,
 - (B) the requirement, or lack of requirement, for leak testing, or for testing any on/off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity, and
 - (C) the information called for in 1 of the following statements, as appropriate, in the same or substantially similar form:
 - (I) The receipt, possession, use and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the US nuclear regulatory commission or a state with which the US nuclear regulatory commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

MATERIAL

CAUTION--RADIOACTIVE

-

distributor)

(Name of manufacturer or

- (II) The receipt, possession, use, and transfer of this device, Model , Serial No. , are subject to a general license or the equivalent, and the regulations of a licensing state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

MATERIAL

CAUTION--RADIOACTIVE

-

distributor)

(Name of manufacturer or

- (D) The model, serial number, and name of the manufacturer or distributor may be omitted from the foregoing label provided the information is elsewhere specified in labeling affixed to the device.
- (b) In the event the applicant desires that the device be required to be tested at intervals longer than 6 months, either for proper operation of the on/off mechanism and indicator, if any, or for leakage of radioactive material or for both, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on/off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the department will consider information which includes, but is not limited to:
 - (i) primary containment (source capsule) ;
 - (ii) protection of primary containment;
 - (iii) method of sealing containment;
 - (iv) containment construction material;
 - (v) form of contained radioactive material;
 - (vi) maximum temperature withstood during prototype tests;
 - (vii) maximum pressure withstood during prototype tests;
 - (viii) maximum quantity of contained radioactive material;
 - (ix) radiotoxicity of contained radioactive material; and
 - (x) operating experience with identical devices or similarly designed and constructed devices.
- (c) In the event the applicant desires that the general license under ARM 37.14.512 (4) or under equivalent regulations of the US nuclear regulatory commission, an agreement state or a licensing state be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on/off mechanism and indicator, or remove the device from installation, he shall include in his application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10% of the limits specified in the table in ARM 37.14.705 (2) .
- (d) Each person licensed under (4) to distribute devices to generally licensed persons shall:
 - (i) Furnish a copy of the general license contained in ARM 37.14.512 (4) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in ARM 37.14.512 (4) .

- (ii) Furnish a copy of the general license contained in the US nuclear regulatory commission's, agreement state's or licensing state's regulation equivalent to ARM 37.14.512 (4) or alternatively, furnish a copy of the general license contained in ARM 37.14.512 (4) , to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the US nuclear regulatory commission, the agreement or the licensing state. If a copy of the general license in ARM 37.14.512 (4) is furnished to such person, it shall be accompanied by a note explaining that the use of the device is regulated by the US nuclear regulatory commission, agreement state or licensing state under requirements substantially the same as those in ARM 37.14.512 (4) .
- (iii) Report to the department all transfers of such devices to persons for use under the general license in ARM 37.14.512 (4) . Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the department and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If 1 or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under ARM 37.14.512 (4) during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter.
- (iv) Reports to other agencies include:
 - (A) Report to the US nuclear regulatory commission all transfers of such devices to persons for use under the US nuclear regulatory commission general license.
 - (B) Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to ARM 37.14.542 (4) for use under a general license in that state's regulations equivalent to ARM 37.14.512 (4) .
 - (C) Such reports shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the department and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If 1 or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person.
 - (D) If no transfers have been made to US nuclear regulatory commission licensees during the reporting period, this information shall be reported to the US nuclear regulatory commission.
 - (E) If no transfers have been made to general licensees within a particular state during the reporting period, this information shall be reported to the responsible state agency upon request of the agency.

- (5) An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under ARM 37.14.512 (5) will be approved subject to the following conditions:
- (a) The applicant satisfies the general requirements specified in ARM 37.14.521 , and
 - (b) the applicant satisfies the requirements of 10 CFR Part 32, sections 32.53, 32.54, 32.55, 32.56, 32.101, or their equivalent.
- (6) An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under ARM 37.14.512 (7) will be approved subject to the following conditions:
- (a) The applicant satisfies the general requirement of ARM 37.14.521 and
 - (b) the applicant satisfies the requirements of 10 CFR Part 32, sections 32.57, 32.58, 32.59, 32.102, and 10 CFR Part 70, section 70.39, or their equivalent.
- (7) In addition to requirements set forth in ARM 37.14.521 , a specific license authorizing the distribution of radioactive material for use by physicians under the general license in ARM 37.14.512 (8) will be issued if:
- (a) the applicant submits evidence that the radioactive material is to be manufactured, labeled, and packaged in accordance with a new drug application which the commissioner of food and drugs, food and drug administration, has approved, or in accordance with a license for a biologic product issued by the secretary, department of health, education, and welfare; and
 - (b) one 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 the label affixed to the container or appears in the leaflet or brochure which accompanies the package:
 - (i) This radioactive drug may be received, possessed, and used only by physicians licensed in the practice of medicine. Its receipt, possession, use and transfer are subject to the regulations and a general license or its equivalent 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)

- (ii) This radioactive drug may be received, possessed, and used only by physicians licensed in the practice of medicine. Its receipt, possession, use and transfer are subject to the regulations and a general license or its equivalent of a licensing state.

(Name of manufacturer)

- (8) An application for a specific license to manufacture or distribute radioactive material for use under the general license of ARM 37.14.512 (9) will be approved if:
- (a) The applicant satisfies the general requirements specified in ARM 37.14.521 .
 - (b) The radioactive material is to be prepared for distribution in prepackaged units of:
 - (i) Iodine-125 in units not exceeding 10 microcuries each.
 - (ii) Iodine-131 in units not exceeding 10 microcuries each.
 - (iii) Carbon-14 in units not exceeding 10 microcuries each.
 - (iv) Hydrogen-3 (tritium) in units not exceeding 50 microcuries each.
 - (v) Iron-59 in units not exceeding 20 microcuries each.
 - (vi) Cobalt-57 in units not exceeding 10 microcuries each.
 - (vii) Selenium-75 in units not exceeding 10 microcuries each.
 - (viii) Mock iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.
 - (c) Each prepackaged unit bears a durable, clearly visible label:
 - (i) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries of hydrogen-3 (tritium) ; 20 microcuries of iron-59; or mock iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each; and
 - (ii) displaying the radiation caution symbol described in ARM 37.14.725 (1) (a) and the words, "CAUTION--RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".
 - (d) One 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:
 - (i) This radioactive material may 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)

- (ii) This radioactive material may 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 label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in ARM 37.14.740 .
- (9) An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under ARM 37.14.512 (10) will be approved subject to the following conditions:
 - (a) the applicant satisfies the general requirements of ARM 37.14.521 , and
 - (b) the criteria of 10 CFR Part 32, sections 32.61, 32.62, 32.103, are met.
 - (10) An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to ARM 37.14.540 (3) for the uses listed in Group I, Group II, IV, or V of Schedule C of this subchapter will be approved if:
 - (a) The applicant satisfies the general requirements specified in ARM 37.14.521 ;
 - (b) The applicant submits evidence that:
 - (i) the radiopharmaceutical containing radioactive material will be manufactured, labeled, and packaged in accordance with the federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the food and drug administration (FDA) , a biologic product license issued by FDA or a "Notice of claimed investigational exemption for a new drug" (IND) that has been accepted by the FDA, or
 - (ii) the manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the federal Food, Drug and Cosmetic Act and the Public Health Service Act;
 - (c) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by group licensees; and
 - (d)
 - (i) The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity, and date of assay and the label affixed to each package, or

the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the department for distribution to persons licensed pursuant to ARM

- (ii) The labels, leaflets or brochures required by (d) (i) above are in addition to the labeling required by the food and drug administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.
- (11) An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to ARM 37.14.540 (3) for the uses listed in Group II of Schedule C of this subchapter will be approved if:
- (a) The applicant satisfies the general requirements specified in ARM 37.14.521 ;
 - (b) the applicant submits evidence that:
 - (i) the generator or reagent kit is to be manufactured, labeled and packaged in accordance with the federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the food and drug administration (FDA) , a biologic product license issued by FDA, or a "Notice of claimed investigational exemption for a new drug" (IND) that has been accepted by the FDA, or
 - (ii) the manufacture and distribution of the generator or reagent kit are not subject to the federal Food, Drug and Cosmetic Act and the Public Health Service Act;
 - (c) the applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or the reagent kit;
 - (d) the label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and
 - (e) the label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:
 - (i) adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in elating the generator or processing radioactive material with the reagent kit, and
 - (ii) a statement that this generator or reagent kit (as appropriate) is approved for use by persons licensed by the department pursuant to ARM 37.14.540 (3) and Schedule C, Group III of this subchapter or under equivalent licenses of the US nuclear regulatory commission, an agreement state or a licensing state. The labels, leaflets or brochures required by (11) are in addition to the labeling required by FDA and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

NOTE: Although the department does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his reagent kits approved by the department for use by persons licensed pursuant

to ARM 37.14.540 (3) and Group III of Schedule C of this subchapter may submit the pertinent information specified in (11) .

- (12) An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to ARM 37.14.540 (3) for use as a calibration or reference source or for the uses listed in Group VI of Schedule C of this subchapter will be approved if:
- (a) The applicant satisfies the general requirements in ARM 37.14.521 .
 - (b) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:
 - (i) the radioactive material contained, its chemical and physical form, and amount,
 - (ii) details of design and construction of the source or device,
 - (iii) procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,
 - (iv) for devices containing radioactive material, the radiation profile of a prototype device,
 - (v) details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,
 - (vi) procedures and standards for calibrating sources and devices,
 - (vii) legend and methods for labeling sources and devices as to their radioactive content, and
 - (viii) instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label.
 - (c) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the name of source or device is licensed by the department for distribution to persons licensed pursuant to ARM 37.14.540 (3) and Schedule C, Group VI of this subchapter or under equivalent licenses of the US nuclear regulatory commission, an agreement state or a licensing state, provided, that such labeling for sources which do not require long term storage (e.g., gold-198 seeds) may be on a leaflet or brochure which accompanies the source.
 - (d) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than 6 months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

- (e) In determining the acceptable interval for test of leakage of radioactive material, the department will consider information that includes, but is not limited to:
 - (i) primary containment (source capsule) ,
 - (ii) protection of primary containment,
 - (iii) method of sealing containment,
 - (iv) containment construction materials,
 - (v) form of contained radioactive material,
 - (vi) maximum temperature withstood during prototype tests,
 - (vii) maximum pressure withstood during prototype tests,
 - (viii) maximum quantity of contained radioactive material,
 - (ix) radiotoxicity of contained radioactive material, and
 - (x) operating experience with identical sources or devices or similarly designed and constructed sources or devices.
- (13) Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass-volume applications.
 - (a) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to ARM 37.14.511 (4) or equivalent regulations of the US nuclear regulatory commission or an agreement state will be approved if:
 - (i) the applicant satisfies the general requirements specified in ARM 37.14.521 ;
 - (ii) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of 1 calendar quarter a radiation dose in excess of 10% of the limits specified in ARM 37.14.705 (2) ; and
 - (iii) the applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.
 - (b) In the case of an industrial product or device whose unique benefits are questionable, the department will approve an application for a specific license under (13) only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.
 - (c) The department may deny any application for a specific license under (13) if the end use(s) of the industrial product or device cannot be reasonably foreseen.
 - (d) Each person licensed pursuant to (a) above shall:

- (i) maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;
- (ii) label or mark each unit to:
 - (A) identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and
 - (B) state that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the US nuclear regulatory commission or of an agreement state;
- (iii) assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";
- (iv)
 - (A) furnish a copy of the general license contained in ARM
 - (B) furnish a copy of the general license contained in the US nuclear regulatory commission's or agreement state's regulation equivalent to ARM 37.14.511 (4) and a copy of the US nuclear regulatory commission's or agreement state's certificate, or alternatively, furnish a copy of the general license contained in ARM 37.14.511 (4) and a copy of department form MRH-12 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the US nuclear regulatory commission or an agreement state, with a note explaining that use of the product or device is regulated by the US nuclear regulatory commission or an agreement state under requirements substantially the same as those in ARM 37.14.511 (4) ;
- (v) report to the department all transfers of industrial products or devices to persons for use under the general license in ARM 37.14.511 (4) . Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the department and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under ARM 37.14.511 (4) during the reporting period, the report shall so indicate;
- (vi)
 - (A) report to the US nuclear regulatory commission all transfers of industrial products or devices to persons for use under the US nuclear regulatory commission general license,
 - (B) report to the responsible state agency all transfers of devices manufactured and distributed pursuant to (13) for use under a general license in that state's regulations equivalent to ARM 37.14.511 (4) ,

- (C) such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person,
 - (D) if no transfers have been made to US nuclear regulatory commission licensees during the reporting period, this information shall be reported to the US nuclear regulatory commission,
 - (E) if no transfers have been made to general licensees within a particular agreement state during the reporting period, this information shall be reported to the responsible agreement state agency; and
- (vii) keep records showing the name, address, and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in ARM 37.14.511 (4) or equivalent regulations of the US nuclear regulatory commission or of an agreement state. The records shall be maintained for a period of 2 years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this subchapter.

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.