DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

RADIATION CONTROL - LICENSING OF RADIOACTIVE MATERIAL

6 CCR 1007-1 PART 03

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

LICENSING OF RADIOACTIVE MATERIAL

3.1 Purpose and Scope

3.1.1 Authority.

3.1.1.1 Rules and regulations set forth herein are adopted pursuant to the provisions of sections 25 1 108, 25 1.5 101(1)(k) and (1)(l), and 25 11 104, CRS.

3.1.2 Basis and Purpose.

3.1.2.1 A statement of basis and purpose of these regulations is incorporated as part of these regulations; a copy may be obtained from the Department.

3.1.3 Scope.

3.1.3.1 This part, and Parts 5, 7, 14, 16, 17, 18, and 19 of these regulations, provide for the licensing of radioactive material.

3.1.3.2 No person shall receive, possess, own, acquire, process, use, store, transfer, or dispose radioactive material except as authorized pursuant to this part or Parts 5, 7, 14, 17, 18, or 19 of these regulations, or as otherwise provided in these parts.

3.1.4 Applicability.

3.1.4.1 In addition to the requirements of this part, all licensees are subject to the requirements of Parts 1, 4, 10, 12 and 17.

3.1.4.2 Furthermore:

(1) Licensees engaged in industrial radiographic operations are subject to the requirements of Part 5.

(2) Licensees using radionuclides in the healing arts are subject to the requirements of Part 7.

(3) Licensees engaged in land disposal of radioactive material are subject to the requirements of either Part 14 or Part 18, as appropriate.

(4) Licensees engaged in source material milling are subject to the requirements of Part 18.

(5) Licensees engaged in wireline and subsurface tracer studies are subject to the requirements of Part 16.

(6) Panoramic or underwater irradiator licensees are subject to the requirements of Part 19.

3.1.5 Definitions

3.1.5.1 Definitions of general applicability to these regulations are in Part 1, Section 1.2.

3.1.5.2 As used in Part 3, each term below has the definition set forth.

“Consortium” means an association of medical use licensees and a Positron Emission Tomography (PET) radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.

3.1.6 The Department may engage the services of qualified persons in order to assist the Department in meeting the requirements of these regulations, including, but not limited to, evaluating information that may be required under 3.8.8.

3.1.6.1 Fees for these services may be charged by the Department as a part of fees charged for radiation control services under Part 12.

EXEMPTIONS FROM THE REGULATORY REQUIREMENTS

3.2 Exemption Of Source Material

3.2.1 Any person is exempt from this part to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20th of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy.

3.2.2 Any person is exempt from this part to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

3.2.3 Any person is exempt from this part to the extent that such person receives, possesses, uses, or transfers an item containing uranium or thorium listed in Schedule 3C, Sections 3C.1, 3C.2, 3C.3, 3C.4, 3C.5, 3C.6, 3C.7, 3C.8 or 3C.9.

3.2.3.1 The exemptions listed in Schedule 3C do not authorize the manufacture of any of the products described.

3.3 Exemption Of Radioactive Material Other Than Source Material.

3.3.1 Exempt Concentrations.

3.3.1.1 Except as provided in 3.3.1.2, any person is exempt from this part to the extent that such person receives, possesses, uses, transfers, or acquires products containing radioactive material introduced in concentrations not in excess of those listed in Schedule 3A.

(1) A manufacturers, processor, or producer that transfers a product or material is exempt so long as concentrations less than those listed in schedule 3A were introduced under an NRC license so authorizing.

(2) Transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being, is not exempt under 3.3.1.1(1).

3.3.1.2 No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under 3.3.1.1 or equivalent regulations of NRC or any Agreement State, except in accordance with a specific license issued consistent with 3.12.1 or the general license provided in 3.24.

3.3.2 Exempt Quantities.

3.3.2.1 Except as provided in 3.3.2.3 and 3.3.2.4, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Schedule 3B.

3.3.2.2 Any person who possesses radioactive material received or acquired under the general license formerly provided under 10 CFR 31.4 before September 25, 1971 is exempt from the requirements for a license set forth in this part to the extent that such person possesses, uses, transfers or owns such radioactive material.

3.3.2.3 Section 3.3.2 does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

3.3.2.4 No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Schedule 3B, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under 3.3.2 or equivalent regulations of NRC or any Agreement State except in accordance with a specific license issued by NRC pursuant to Section 32.18 of 10 CFR Part 32 (January 1, 2013), which license states that the radioactive material may be transferred by the licensee to persons exempt under 3.3.2 or the equivalent regulations of NRC or an Agreement State. [1]

1 Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

3.3.2.5 No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in Schedule 3B, except for a device placed in use before May 3, 1999, or as otherwise permitted by these regulations.

3.3.3 Exempt Items.

3.3.3.1 Any person is exempt from this part to the extent that such person receives, possesses, uses, or transfers an item containing radioactive material which is listed in Schedule 3C, Sections 3C.10, 3C.11, 3C.12, OR 3C.13.

LICENSES

3.4 Types of Licenses.

Licenses for radioactive materials are of two types: general and specific.

3.4.1 A general license is provided by regulation and grants authority to a person for certain activities involving radioactive material.

3.4.1.1 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.

3.4.1.2 However, registration or filing of a certificate with the Department may be required by the particular general license.

3.4.1.3 The general licensee is subject to all other applicable portions of these regulations and any limitations of the general license.

3.4.2 A specific license requires the submission of an application to the Department and the issuance of a licensing document by the Department.

3.4.2.1 The licensee is subject to all applicable portions of these regulations as well as any limitations specified in the licensing document.

GENERAL LICENSES

3.5 General Licenses - Source Material.

3.5.1 A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and State and local government agencies to use and transfer not more than 6.82 kg (15 pounds) of source material at any one time for research, development, educational, commercial, or operational purposes.

3.5.1.1 A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 68.2 kg (150 pounds) of source material in any one calendar year.

3.5.1.2 Persons who receive, possess, use or transfer source material pursuant to the general license in 3.5.1 are prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized in a specific license.

3.5.2 Persons who receive, possess, use, or transfer source material pursuant to the general license issued in 3.5.1 are exempt from the provisions of Parts 4 and 10 to the extent that such receipt, possession, use, or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to this part.

3.5.3 A general license is hereby issued authorizing the receipt of title to source material without regard to quantity.

3.5.3.1 This general license does not authorize any person to receive, possess, use, or transfer source material.

3.5.4 A general license is hereby issued authorizing the possession of source material involved in mining operations provided such operations meet the regulatory requirements of the Division of Reclamation, Mining and Safety, Colorado Department of Natural Resources, or any successor thereto, and, except as authorized in a specific license, such mining operations shall not refine or process such ore.

3.5.5 Depleted Uranium in Industrial Products and Devices.

3.5.5.1 A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 3.5.5.2, 3.5.5.3, 3.5.5.4, and 3.5.5.5, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

3.5.5.2 The general license in 3.5.5.1 applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 3.12.13 or in accordance with a specific license issued to the manufacturer by NRC or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by NRC or an Agreement State.

(1) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 3.5.5.1 shall file Department Form R-52, "Registration Certificate - Use of Depleted Uranium Under General License", with the Department.

(a) The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium.

(b) The general licensee shall furnish on Department Form R-52 the following information and such other information as may be required by that form:

(i) Name and address of the general licensee;

(ii) A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 3.5.5.1 and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(iii) Name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in 3.5.5.3(1)(b)(ii).

(2) The general licensee possessing or using depleted uranium under the general license established by 3.5.5.1 shall report in writing to the Department any changes in information furnished by him in Department Form R-52, "Registration Certificate - Use of Depleted Uranium Under General License". The report shall be submitted within 30 days after the effective date of such change.

3.5.5.4 A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by 3.5.5.1:

(1) Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

(2) Shall not abandon such depleted uranium;

(3) Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 3.22.

(a) In the case where the transferee receives the depleted uranium pursuant to the general license established by 3.5.5.1, the transferor shall furnish the transferee a copy of this regulation and a copy of Department Form R-52.

(b) In the case where the transferee receives the depleted uranium pursuant to a general license contained in NRC's or Agreement State's regulation equivalent to 3.5.5.1, the transferor shall furnish the transferee a copy of this regulation and a copy of Department Form R-52 accompanied by a note explaining that use of the product or device is regulated by NRC or Agreement State under requirements substantially the same as those in this regulation;

(4) Within 30 days of any transfer, shall report in writing to the Department the name and address of the person receiving the depleted uranium pursuant to such transfer, and

(5) Shall not export such depleted uranium except in accordance with a license issued by NRC pursuant to 10 CFR Part 110 (January 1, 2013).

3.5.5.5 Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 3.5.5.1 is exempt from the requirements of Parts 4 and 10 with respect to the depleted uranium covered by that general license.

3.6 General Licenses [2] - Radioactive Material Other Than Source Material.

2 Different general licenses are issued in this section, each of which has its own specific conditions and requirements.

3.6.1 Certain Devices and Equipment.

3.6.1.1 A general license is hereby issued to transfer, receive, acquire, own, 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 NRC for use pursuant to Section 31.3 of 10 CFR Part 31 (January 1, 2013).

(1) 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 18.5 MBq (500 µCi) of polonium-210 per device.

(2) Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 µCi) of polonium-210 per device or a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

3.6.1.2 This general license is subject to the provisions of 1.4 through 1.9, 3.3.1.2, 3.15, 3.22, and 3.23, part 4 [3] , part 10 and part 17.

3 Attention is directed particularly to the provisions of Part 4 which relate to the labeling of containers.

3.6.2 Reserved.

3.6.3 Reserved.

3.6.4 Certain Measuring, Gauging or Controlling Devices.

3.6.4.1 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 3.6.4.2, 3.6.4.3, and 3.6.4.4, 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.

3.6.4.2 The general license in 3.6.4.1 applies only to radioactive material contained in devices which have been:

(1) Manufactured or initially transferred and labeled for distribution to persons generally licensed in accordance with the specifications contained in a specific license issued by:

(a) The Department pursuant to 3.12.4 or

(b) By NRC or an Agreement State [4]

4 Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21 (April 1, 2012).

(2) Received from one of the specific licensees described in 3.6.4.2(1) or through a transfer made under 3.6.4.3(8).

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 µCi) of other beta- and/or gamma-emitting material or 0.37 MBq (10 µCi) 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 the tests required by 3.6.4.3(2) of this section and 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, NRC or an Agreement 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).

(a) The records shall show the results of tests.

(b) 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.

(c) Records of tests for leakage of radioactive material required by 3.6.4.3(2) shall be maintained for 3 years after the next required leak test is performed or until the sealed source is transferred or disposed of.

(d) Records of tests of the "on-off" mechanism and indicator required by 3.6.4.3(2) shall be maintained for 3 years after the next required test of the "on-off" mechanism and indicator is performed or until the sealed source is transferred or disposed of.

(e) Records which are required by 3.6.4.3(3) shall be maintained for a period of 3 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 µCi) or more removable radioactive material, shall immediately suspend operation of the device and shall:

(a) Not operate the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the Department, NRC or an Agreement State to repair such devices;

(b) Ensure that, if dispositioned, the device and any radioactive material from the device is disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device;

(c) Within 30 days, furnish to the Department a report containing a brief description of the event and the remedial action taken; and

(d) 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, 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.

(i) 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, 2013) and shall obtain written approval from NRC 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:

(a) Only by transfer to a specific licensee of the Department, NRC or an Agreement State whose specific license authorizes receipt of the device; and

(b) Within 30 days after transfer or export, shall furnish to the Department a report containing:

(i) Identification of the device by manufacturer's (or initial transferor's) name, model number and serial number;

(ii) The name, address and license number of the person receiving the device;

(iii) The date of the transfer;

(iv) The identity of the radionuclide(s) present and activity present, by assay or calculation;

(c) Comply with 10 CFR 31.5(c)(8)(iii), as applicable.

(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.

(a) 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.

(a) 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, 3.7 MBq (0.1 mCi) of radium-226, 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. Each address for a location of use, as described in 3.6.4.3(13)(b)(iv) of this section, represents a separate general licensee and requires a separate registration and fee.

(a) Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Department.

(i) 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.

(a) 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.

(a) If a device with shutters is not being used, the shutter must be locked in the closed position.

(b) The testing required by 3.6.4.3(2) need not be performed during the period of storage only.

(c) 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.

(d) 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.

3.6.4.4 The general license in 3.6.4.1 does not authorize the manufacture of devices containing radioactive material.

3.6.4.5 The general license provided in 3.6.4.1 is subject to the provisions of 1.4 through 1.9, 3.15, 3.22, 3.23 and Part 17.

3.6.5 Luminous Safety Devices for Aircraft.

3.6.5.1 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:

(1) Each device contains not more than 370 GBq (10 Ci) of tritium or 11.1 GBq (300 mCi) of promethium-147; and

(2) Each device has been manufactured, assembled or imported in accordance with a specific license issued by NRC 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 pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32 (January 1, 2013).

3.6.5.2 Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in 3.6.5.1 are exempt from the requirements of Parts 4 and 10 except that they shall comply with the provisions of 4.51 and 4.52.

3.6.5.3 This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

3.6.5.4 This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

3.6.5.5 This general license is subject to the provisions of 1.4 through 1.9, 3.15, 3.22, 3.23, and Part 17.

3.6.6 Ownership of Radioactive Material.

3.6.6.1 A general license is hereby issued to own radioactive material without regard to quantity.

3.6.6.2 Notwithstanding any other provisions of this part, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

3.6.7 Calibration and Reference Sources.

3.6.7.1 A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of 3.6.7.4 and 3.6.7.5, americium-241 in the form of calibration or reference sources:

(1) Any person who holds a specific license issued by the Department which authorizes him to receive, possess, use, and transfer radioactive material; and

(2) Any person who holds a specific license issued by NRC which authorizes him to receive, possess, use, and transfer special nuclear material.

3.6.7.2 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 3.6.7.4 and 3.6.7.5 to any person who holds a specific license issued by the Department which authorizes him to receive, possess, use, and transfer radioactive material.

3.6.7.3 A general license is hereby issued to own, receive, possess, use, and transfer radium 226 in the form of calibration or reference sources in accordance with the provisions of 3.6.7.4 and 3.6.7.5 to any person who holds a specific license issued by the Department which authorizes him to receive, possess, use, and transfer radioactive material.

3.6.7.4 The general licenses in 3.6.7.1, 3.6.7.2, and 3.6.7.3 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 NRC

pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 (January 1, 2013) or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Department or any Agreement State pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 (January 1, 2013).

3.6.7.5 The general licenses provided in 3.6.7.1, 3.6.7.2, and 3.6.7.3 are subject to the provisions of 1.4 through 1.9, 3.15, 3.22, 3.23 and 3.24, and Parts 4 and 10. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses, shall:

(1) Not possess at any one time, at any one location of storage or use, more than 185 kBq (5 µCi) of americium-241, 185 kBq (5 µCi) of plutonium, or 185 kBq (5 µCi) of radium-226 in such sources;

(2) Not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one 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 U.S. Nuclear Regulatory Commission or an Agreement State. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS (AMERICIUM-241) (PLUTONIUM) (RADIUM-226). [5] DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

Name of manufacturer or importer

5 Showing only the name of the appropriate material.

(3) Not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Department, NRC or an Agreement State to receive the source;

(4) 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

(5) Not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

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

3.6.8 Reserved.

3.6.9 General License for Use of Radioactive Material for Certain *In Vitro* Clinical or Laboratory Testing. [6]

6 The New Drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

3.6.9.1 A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 3.6.9.2, 3.6.9.3, 3.6.9.4, 3.6.9.5, and 3.6.9.6, the following radioactive materials in prepackaged units 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:

(1) Carbon-14, in units not exceeding 370 kBq (10 µCi) each;

(2) Cobalt-57, in units not exceeding 370 kBq (10 µCi) each;

(3) Hydrogen-3 (tritium), in units not exceeding 1.85 MBq (50 µCi) each;

(4) Iodine-125, in units not exceeding 370 kBq (10 µCi) each;

(5) Mock Iodine-125 reference or calibration sources, in units not exceeding 1.85 kBq (0.05 µCi) of iodine-129 and 185 Bq (0.005 µCi) of americium-241 each;

(6) Iodine-131, in units not exceeding 370 kBq (10 µCi) each;

(7) Iron-59, in units not exceeding 740 kBg (20 µCi) each; or

(8) Selenium-75, in units not exceeding 370 kBq (10 µCi) each.

3.6.9.2 No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by 3.6.9.1 until the person has filed Department Form R-27, "Certificate - *In Vitro* Testing with Radioactive Material Under General License", with the Department and received from the Department a validated copy of Department Form R-27 with certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish on Department Form R-27 the following information and such other information as may be required by that form:

(1) Name and address of the physician, veterinarian, clinical laboratory or hospital;

(2) The location of use; and

(3) A statement that the physician, veterinarian, 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 3.6.9.1 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.

3.6.9.3 A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by 3.6.9.1 shall comply with the following requirements.

(1) The general licensee shall not possess at any one time, pursuant to the general license in 3.6.9.1, at any one location of storage or use, a total amount of iodine 125, iodine 131, selenium 75, iron 59, and/or cobalt 57 in excess of 7.4 MBq (200 µCi).

(2) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(3) The general licensee shall use the radioactive material only for the uses authorized by 3.6.9.1.

(4) 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, NRC or any Agreement State nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(5) The general licensee shall dispose of the Mock Iodine 125 reference or calibration sources described in 3.6.9.1(5) as required by 4.33.

3.6.9.4 The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to 3.6.9.1:

(1) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 3.12.8 or in accordance with the provisions of a specific license issued by NRC or any Agreement 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 3.6.9 or its equivalent; and

(2) Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one 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, veterinarians, 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 U.S. Nuclear Regulatory Commission or an Agreement State.

_____

Name of manufacturer

3.6.9.5 The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of 3.6.9.1 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 R-27. The report shall be furnished within 30 days after the effective date of such change.

3.6.9.6 Any person using radioactive material pursuant to the general license of 3.6.9.1 is exempt from the requirements of Part 4 and 10 with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in 3.6.9.1(5) shall comply with the provisions of 4.33, 4.51 and 4.52.

3.6.10 Ice Detection Devices.

3.6.10.1 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 1.85 MBq (50 µCi) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by NRC or each device has been

manufactured in accordance with the specifications contained in a specific license issued by the Department or an Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32 (January 1, 2013).

3.6.10.2 Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in 3.6.10.1:

(1) 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 NRC or an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of 4.33;

(2) 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

(3) Are exempt from the requirements of Parts 4 and 10 except that such persons shall comply with the provisions of 4.33, 4.51, and 4.52.

3.6.10.3 This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

3.6.10.4 This general license is subject to the provisions of 1.4 through 1.9, 3.15, 3.22, 3.23 and Part 17.

3.7 Reserved.

SPECIFIC LICENSES

3.8 Filing An Application for A Specific License.

3.8.1 Applications for specific licenses shall be filed on a form prescribed by the Department.

3.8.2 The Department may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Department to determine whether the application should be granted or denied or whether a license should be modified or revoked.

3.8.3 Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on the applicant's or licensee's behalf.

3.8.4 An application for a license may include a request for a license authorizing one or more activities.

3.8.5 In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Department provided such references are clear and specific.

3.8.6 Applications and documents submitted to the Department may be made available for public inspection except that the Department may withhold any document or part thereof from public inspection pursuant to 24-72-204, CRS.

3.8.7 Pre-licensing Construction

3.8.7.1 An application for a license, or to amend or renew an existing license, for (1) source material milling, (2) commercial waste storage, treatment or disposal by incineration, (3) transfer for disposal of wastes from treatment or incineration, (4) commercial waste disposal by land burial or by underground injection, or the (5) conduct of any other activity within the licensing authority of the Department which the Department determines will significantly affect the radiological quality of the human environment, shall be filed with the Department at least nine (9) months prior to the anticipated commencement of construction of the plant or facility in which the activity will be conducted or in accordance with the requirements of Part 18 if applicable, and shall be accompanied by the environmental report required by 3.8.8, unless an exemption from the requirement of furnishing such a report has been obtained from the Department.

3.8.7.2 No construction shall be commenced until the license has been issued.

3.8.7.3 For the purpose of 3.8.7 the term "commencement of construction" means any clearing of land, excavation or other substantial action related to a proposed activity for specific licensing that would adversely affect the natural environment of a site; this term does not include changes desirable for the temporary use of the land for public recreational uses, limited borings to determine site characteristics as necessary for environmental assessment of other pre-construction monitoring to establish background information related to the suitability of a site, or to the protection of environmental values.

3.8.8 Environmental Impact Assessment.

3.8.8.1 In the case of an application for a license, or to amend or renew an existing license, for (1) source material milling, (2) commercial waste storage, treatment or disposal by incineration, (3) transfer for disposal of waste from incineration, (4) commercial waste disposal by land burial or by underground injection, or for (5) the conduct of any other activity which will affect the quality of the human environment by reason of exposure to radiation, before "commencement of construction", as defined in 3.8.7.3, of the plant or facility in or at which the activity will be conducted, or in case of a renewal of such a license, the applicant shall submit all information required under these regulations and such other material as the Department may deem necessary.

(1) Such information shall include the environmental report and other information required by 3.8.8.2 to be submitted to assist the Department in the evaluation of the short-term and long-range environmental impact of the project and activity so that the Department may weigh environmental, economic, technical, and other benefits against environmental costs, while considering available alternatives.

(2) In the event that an environmental report acceptable to the Department is on file with the Department in regard to the specific licensed activity authorized under an existing license, and upon request of the applicant to amend or renew an existing license or at the initiation of the Department, the Department may grant an exemption of the requirement to submit an additional environmental report or require such amendment of the existing environmental report as will demonstrate the environmental impact to result from the proposed activity.

(3) The request for exemption shall provide the Department with such information as the Department requires of the applicant to demonstrate that no significant environmental impact will result from the licensed activity.

3.8.8.2 An environmental report shall be required of the applicant and shall contain all information deemed necessary by the Department as required by the Act.

(1) Upon receipt of the environmental report or any amendment thereto, and of any other documents required, the Department shall determine the necessity to transmit and, if appropriate, shall transmit the same for review and comment to Federal, State, and local agencies having expertise in and jurisdiction over the proposed project and activity.

(2) Written comments and reports of reviewing agencies shall be considered by the Department in its decision-making review process on the license application request.

(3) If an environmental impact statement (EIS) is required of a Federal agency pursuant to the National Environment Policy Act of 1969 (NEPA) and is provided by such Federal agency, it shall be used by the Department in its decision-making review process on the license application request.

(4) The Department shall consider applicable regulations of Federal, State, and local regulatory agencies and permit requirements thereof.

3.8.9 An application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source shall either:

3.8.9.1 Identify the source or device by manufacturer and model number as registered with the NRC under 10 CFR 32.210 or with an Agreement State, or for a source or a device containing radium-226 or accelerator produced radioactive material with an Agreement State under provisions comparable to 10 CFR 32.210; or

3.8.9.2 Contain the information contained in 10 CFR 32.210(c); or

3.8.9.3 For sources or devices containing naturally occurring or accelerator-produced radioactive material manufactured prior to November 30, 2007 that are not registered with the NRC under 10 CFR 32.210 or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c), the applicant must provide:

(1) All available information identified in 10 CFR 32.210(c) concerning the source, and, if applicable, the device; and

(2) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

3.8.10 An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under Part 7 of these regulations or equivalent Agreement State requirements shall include:

3.8.10.1 A request for authorization for the production of PET radionuclides or evidence of an existing license issued under this Part or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

3.8.10.2 Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 3.12.10.1(2).

3.8.10.3 Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in 3.12.10.2(2).

3.8.10.4 Information identified in 3.12.10.1(3) on the PET drugs to be noncommercially transferred to members of its consortium.

3.9 General Requirements for the Issuance of Specific Licenses.

A license application will be approved if the Department determines that:

3.9.1 The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these regulations in such a manner as to minimize danger to public health and safety or property;

3.9.2 The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property and the applicant's facilities are permanently located in Colorado;

3.9.3 The issuance of the license will not be inimical to the health and safety of the public;

3.9.4 The applicant satisfies any applicable special requirements in 3.10, 3.11, or 3.12; and

3.9.5 The applicant has established Department-approved financial assurance warranties in accordance with the following requirements.

3.9.5.1 A signed executed original copy of each warranty required by this part shall be furnished to and approved by the Department prior to the issuance of a new license, or any amendment or renewal of an existing license.

3.9.5.2 The Department may require any licensee to furnish a decommissioning warranty in a dollar amount determined by the agency as necessary to protect public health and safety, to ensure corrective action during operation, to ensure decontamination and decommissioning of a facility and disposal of radioactive materials in the event of abandonment, default or inability of the licensee to meet the requirements of the Act, these regulations, or the license.

3.9.5.3 The following specific licensees are required to furnish decommissioning warranties:

(1) Each licensee authorized to possess and use greater than 370 MBq (10 mCi) of source material in a readily dispersible form; and

(2) Each licensee authorized to possess and use radioactive material with a half-life greater than 120 days, in quantities:

(a) Greater than 10^3 times the applicable quantity of Schedule 3B in unsealed form. For a combination of isotopes if R divided by 10^3 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Schedule 3B.

(b) Greater than 10^{10} times the applicable quantity of Schedule 3B in sealed sources or plated foils. For a combination of isotopes if R divided by 10^{10} is greater than 1 (unity rule), where R is defined in 3.9.5.3(2)(a).

(c) 370 Bq (0.01 µCi) shall be used as the Schedule 3B value for any alpha emitting radionuclide not listed in Schedule 3B, or mixtures of alpha emitters of unknown composition, for the purpose of determining if the quantity of licensed radioactive material requires a decommissioning warranty or a decommissioning funding plan as defined in 3.9.6.

(3) Former U.S. Atomic Energy Commission or NRC licensed facilities;

(4) Radioactive waste collection and/or processing licensees;

(5) Radioactive waste disposal licensees;

(6) Source material milling licensees;

(7) Ore refineries; and

(8) Other persons with, or applicants for, a specific license as determined by the agency.

3.9.5.4 Acceptable Financial Assurance Methods.

(1) Financial assurance warranties shall contain provisions which are acceptable to the Department for:

(a) Defining the amount and term of the warranty;

(b) Providing written notification to the Department by the warrantor at least ninety (90) days prior to cancellation, termination, or revocation of the warranty; and

(c) Converting the warranty into cash upon forfeiture of the warranty, and

(2) Financial assurance warranties shall be in the form of a cash deposit, prepayment of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(a) Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs; or

(3) Financial assurance warranties which involve a guarantee method to ensure that costs will be paid should the licensee default shall be in a form as described below:

(a) A bond issued by a fidelity or surety company consistent with the provisions of Section 25-11-110(6)(b)(I), CRS;

(b) An irrevocable "letter of credit" or "line of credit" issued by a recognized financial institution whose financial condition and commitment are established to the satisfaction of the Department;

(c) For a decommissioning warranty, a guarantee of funds by the applicant, licensee, or parent company which satisfies the requirements listed below. However, this self-guarantee shall not apply to uranium or thorium milling licensees.

(i) The Department may accept a parent company guarantee of funds for decommissioning costs based upon a financial test of the parent company and a written guarantee as contained in Appendix 3F.

(ii) The Department may accept an applicant or licensee guarantee of funds for decommissioning costs based upon a financial test of the applicant or licensee and a written guarantee as contained in Appendix 3G.

(iii) A guarantee by the applicant, licensee, or parent company may not be used in combination with other financial methods to satisfy the requirements of this section.

(iv) A guarantee by the applicant or licensee may not be used in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company; or

(4) Financial assurance warranties which involve an external sinking fund shall be in a form in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund.

(a) An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected.

(b) An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities; or

(5) Financial assurance warranties previously provided to any State, Federal and/or local governing bodies concerning activities subject to license under these regulations, where the amount, terms, and conditions of such financial assurance warranties have been established to the satisfaction of the Department and in accordance with the requirements of 3.9.5; or

(6) Except for the guarantee of funds noted in 3.9.5.4(3), combinations of the above may be used to establish an acceptable financial assurance warranty.

(7) The term of the financial assurance warranty shall be open-ended or shall have provisions for automatic renewal until termination of the license by the Department, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance.

(8) The value of the financial assurance warranty must not be dependent upon the success, profitability, or continued operation of the licensed business or operation.

3.9.5.5 The amount of funds to be provided by such decommissioning warranties shall be based on Department-approved cost estimates and shall

(1) Include the disposal of radioactive materials;

(2) Include decontamination and decommissioning of buildings, facilities and the site to levels which would allow unrestricted use of these areas upon decommissioning;

(3) Include the reclamation of tailings and/or waste disposal areas in accordance with technical criteria delineated in Parts 3, 4 and/or 18, as appropriate;

(4) Take into account total costs that would be incurred if an independent contractor were hired to dispose of radioactive materials and perform decontamination, decommissioning, and reclamation work, including:

(a) The cost of removal and/or disposal of radioactive material, or a radioactivity-inducing machine, which is or would be generated, stored, processed or otherwise present at the facility or site; and

(b) The probable extent of contamination through the possession or use of radioactive material, at or adjacent to the facility or site, and the probable cost of removal of such contamination; and

(5) Include reasonable administrative costs, including indirect costs, incurred by the Department in conducting or overseeing the decontamination, decommissioning, and disposal activities, and to cover the Department's reasonable attorney costs that may be incurred in successfully revoking, foreclosing, or realizing the decommissioning warranties established by the licensee in accordance with Part 3.

3.9.5.6 The licensee shall provide in writing to the Department, no later than June 30th of each calendar year, an annual report demonstrating proof of the value of existing financial warranties and any licensee-proposed changes to the financial assurance warranties, including updated decommissioning funding plans, cost estimates, or the type of warranty. The annual report shall describe any changes in operations, estimated costs, or any other circumstances that may affect the amount of the required financial assurance warranties, including any increased or decreased costs attributable to inflation.

3.9.5.7 Each licensee's financial assurance warranties shall be subject to review annually by the Department to assure the continued adequacy of each warranty. Public notice of the submittal of the licensee's annual report shall be posted on the Department's web site and published by the licensee in the local paper of general circulation. Any person may submit written comments to the Department concerning the adequacy of any financial assurance warranties. The act of submitting such comments does not provide a right to administrative appeal concerning the financial assurance warranties.

3.9.5.8 The Department will determine if the licensee must adjust the amount of the warranty to account for increases or decreases in cost estimates resulting from inflation or deflation; changes in engineering plans, activities performed, authorized quantities of radioactive material; or changes in any other conditions affecting disposal, decontamination, and decommissioning costs.

(1) With the approval of the Department, a licensee may reduce the amount of a decommissioning warranty as decommissioning activities are completed in

accordance with an approved decommissioning plan and/or to reflect current site conditions and license authorizations.

(2) The licensee shall have sixty days after the date of written notification by the Department of a required adjustment to establish a warranty fulfilling all new requirements unless granted an extension by the Department. If the licensee disputes the amount of the required financial assurance warranties, the licensee may request a hearing to be conducted in accordance with section 24-4-105, CRS.

(3) If the licensee requests a hearing, no new classified material, as that term is defined in 1.2.2, may be brought on site and no classified material may be processed until the licensee's dispute over the financial assurance warranty is resolved, unless the licensee posts a bond in a form approved by the Department equal to the amount in dispute.

3.9.5.9 Regardless of whether the disposal, decontamination and decommissioning work is phased through the life of the licensed operations or takes place at the end of the operation, an appropriate and adequate decommissioning warranty shall be maintained in good standing by the licensee until termination of the license or as otherwise authorized by the Department.

3.9.5.10 In addition to the decommissioning warranty required by 3.9.5.2, the Department may require any licensee to provide a long-term care warranty if the licensed facility will remain a disposal site for radioactive materials subsequent to the termination of the license, or the license will be terminated using criteria in 4.61.3 or 4.61.4.

(1) Except as provided in 3.9.5.10(2), the following specific licensees are required to provide long-term care warranties:

(a) Radioactive waste disposal licensees;

(b) Commercial radioactive waste handling and/or packaging licensees;

(c) Source material milling licensees; and

(d) Formerly U.S. Atomic Energy Commission or U.S. Nuclear Regulatory Commission-licensed facilities;

(2) A long-term care warranty is not required for a licensee identified in 3.9.5.10(1) if the disposition of radioactive materials by the licensee is made in such a manner as the Department determines does not require long-term monitoring and maintenance of the site.

(3) The long-term care warranty shall be in a form as described in 3.9.5.4.

(4) The amount of funds to be provided by such long-term care warranties shall be based on Department-approved cost estimates and shall be enough that with an assumed six percent annual real interest rate, the annual interest earnings will be sufficient to cover the annual costs of site surveillance, including reasonable administrative costs incurred, in perpetuity, subsequent to the termination of the license.

(a) For each source material mill licensee, the long-term care warranty must have a minimum value equivalent to $250,000 in 1978 dollars.

(i) The value of the long-term care warranty shall be adjusted annually to recognize inflation.

(ii) The inflation rate to be used for this adjustment is that indicated by the change in the consumer price index published by the U.S. Department of Labor, Bureau of Labor Statistics.

(iii) The Department may use other indicators of the inflation rate if reasonable; provided, however, that the license shall not terminate unless the amount of the long-term care warranty is acceptable to the licensing agency and site caretaker.

(b) Cost estimates for facilities and sites requiring long-term care subsequent to license termination are to be based on the final disposition of wastes such that ongoing active maintenance is not necessary to preserve isolation.

(i) It is expected that, as a minimum, annual site inspections shall be conducted to confirm the integrity of the stabilized waste systems and to determine the need, if any, for maintenance and/or monitoring.

(ii) Cost estimates shall be adjusted if more frequent site inspections are required based on an evaluation of a particular site.

(c) For sites decommissioned in accordance with the provisions of 4.61.3 or 4.61.4, cost estimates for long-term care subsequent to license termination must be sufficient to enable the Department, a responsible government agency, or an independent third party to:

(i) Perform periodic site inspections no less frequently than each five years;

(ii) Assure the continuation of institutional controls; and

(iii) Assume responsibilities and carry out any necessary control and maintenance of the site. Cost estimates shall be adjusted if more frequent site inspections are required based on an evaluation of a particular site and the institutional controls established for that site.

(5) Whenever the Department determines that a licensee's disposal, decommissioning and decontamination requirements have been satisfied, provisions shall be made for transferring custody of the site and the long-term care warranty funds for that license in accordance with the act.

(a) If the value of the long-term care warranty funds exceeds the amount required by the government agency overseeing the long-term care of the site, then all such excess amounts shall be returned to the licensee.

3.9.6 Decommissioning Funding Plan Required.

3.9.6.1 Each applicant for and holder of a license authorizing the possession and use unsealed radioactive materials with half-life greater than 120 days and in quantities greater than 10^5 times the applicable quantity of Schedule 3B, shall establish a Department-approved

decommissioning funding plan to assure the availability of funds for decommissioning activities conducted over the life of the licensed facility . 370 Bq (0.01 µCi) shall be used as the Schedule 3B value for any alpha emitting radionuclide not listed in Schedule 3B, or mixtures of alpha emitters of unknown composition. A decommissioning funding plan is also required for licensees authorized a combination of isotopes if R divided by 10^{5} is greater than 1 (unity rule), where R is defined in 3.9.5.3(2)(a).

3.9.6.2 Each holder of, or applicant for, any specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities greater than 10^{12} times the applicable quantity in Schedule 3B shall establish a Department-approved decommissioning funding plan to assure the availability of funds for decommissioning activities conducted over the life of the licensed facility. 370 Bq (0.01 µCi) shall be used as the Schedule 3B value for any alpha emitting radionuclide not listed in Schedule 3B, or mixtures of alpha emitters of unknown composition. The decommissioning funding plan is also required for licensees authorized for a combination of isotopes if R divided by 10^{12} is greater than 1 (unity rule), where R is defined as in 3.9.5.3(2)(a).

3.9.6.3 Waste collectors and waste processors, as defined in Part 4, Appendix D, shall establish an agency-approved decommissioning funding plan to assure the availability of funds for decommissioning activities conducted over the life of the licensed facility.

(1) The decommissioning funding plan must include the cost of disposal of the maximum radioactivity (becquerel or curie) of radioactive material permitted by the license, and the cost of disposal of the maximum quantity, by volume, of radioactive material that could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of Part 4.

3.9.6.4 Each decommissioning funding plan must be submitted for review and approval by the Department and must contain:

(1) A detailed cost estimate for decommissioning, in an amount reflecting:

(a) The cost of an independent contractor to perform all decommissioning activities;

(b) The cost of meeting the 4.61.2 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 4.61.3 for restricted use, the cost estimate may be based on meeting the 4.61.3 restricted use criteria;

(c) The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and

(d) An adequate contingency factor.

(i) Identification of and justification for using the key assumptions contained in the detailed cost estimate;

(ii) A description of the method of assuring funds for decommissioning as required in this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility.

(iii) A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

(iv) A signed original, or if permitted, a copy, of the financial instrument obtained to satisfy the requirements of this section (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

3.9.6.5 At the time of license renewal and at intervals not to exceed three years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this can not be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

(1) Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

(2) Waste inventory increasing above the amount previously estimated;

(3) Waste disposal costs increasing above the amount previously estimated;

(4) Facility modifications;

(5) Changes in authorized possession limits;

(6) Actual remediation costs that exceed the previous cost estimate;

(7) Onsite disposal; and

(8) Use of a settling pond.

3.9.6.6 The decommissioning funding plan must also include a certification by the licensee that funding for decommissioning activities has been provided for in the amount of the cost estimate for decommissioning.

(1) For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued, but prior to the receipt or possession of radioactive material.

(2) A signed original of the financial instrument shall be submitted to the Department.

3.9.7 In the case of an application for a license for (1) source material milling, (2) commercial waste storage, treatment or disposal by incineration, (3) transfer for disposal of waste from incineration, (4) commercial waste disposal by land burial or by underground injection, or for (5) the conduct of any other activity which the Department determines will significantly affect the quality of the human environment, the Department has concluded that the action called for is the issuance of the proposed license with any appropriate conditions to protect environmental values.

3.9.7.1 Such determination shall be made before commencement of construction of the plant or facility in which the activity will be conducted and based on information filed and evaluation made pursuant to 3.8.8.

3.9.8 Commencement of construction prior to the issuance of a license, or of an amendment or renewal thereof, or of an exemption under the requirements of 3.8.7, may be grounds for denial of such license, amendment or renewal; and

3.9.9 Reserved.

3.9.10 License Hearings.

3.9.10.1 There shall be an opportunity for public hearings to be held in the following circumstances in accordance with the procedures in 24-4-104 and -105, CRS. and this paragraph:

(1) Prior to the licensing or leasing of state-owned property for the concentration, storage or permanent disposal of radioactive materials.

(2) For each proposed license, five-year license renewal, or license amendment pertaining to a uranium recovery facility's receipt of classified material as specified in Part 18 of these regulations.

3.9.11 Contingency Plans

3.9.11.1 Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in Schedule 3E - "Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release", must contain either:

(1) An evaluation, as described in 3.9.11.2, showing that the projected dose to a person offsite due to a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or

(2) A contingency plan for responding to a release of radioactive material.

3.9.11.2 In evaluating the total effective dose equivalent to an individual pursuant to 3.9.11.1(1):

(1) The radioactive material is physically separated so that only a portion could be involved in an accident;

(2) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(3) The release fraction in the respirable size range is predicted to be lower than the release fraction shown in Schedule 3E due to the chemical or physical form of the material;

(4) The solubility of the radioactive material would reduce the dose received;

(5) Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Schedule 3E.

(6) Operating restrictions or procedures would prevent a release fraction as large as that shown in Schedule 3E.

3.9.11.3 A contingency plan for responding to a release of radioactive material submitted under 3.9.11.1(2) must include the following information, in separate sections having each page numbered and labeled with a revision date and revision number:

(1) Facility description - a brief description of the licensee's facility and surroundings.

(2) Types of accidents - a n identification of each type of accident involving radioactive material for which actions by licensee staff or offsite response organizations will be needed to protect members of the public.

(3) Classification of accidents - a method for classifying and declaring each alert or site area emergency, as defined in Part 1.

(4) Detection of accidents - identification of the means of detecting each type of accident in a timely manner.

(5) Mitigation of consequences - a brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(6) Assessment of releases - a brief description of the methods and equipment to assess releases of radioactive materials.

(7) Responsibilities - a brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the Department; also responsibilities for developing, maintaining, and updating the plan.

(8) Notification and coordination.

(a) A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate.

(b) A control point must be established.

(c) The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination.

(d) The licensee shall also commit to notify the Department immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

(9) Information to be communicated - a brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the Department.

(10) Training.

(a) A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours

the licensee would offer to fire, police, medical and other emergency personnel.

(b) The training shall familiarize personnel with site-specific emergency procedures.

(c) Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(11) Safe shutdown - a brief description of the means of restoring the facility to a safe condition after an accident.

(12) Exercises.

(a) Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies.

(b) Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers.

(c) The licensee shall invite offsite response organizations to participate in the biennial exercises.

(d) Participation of offsite response organizations in biennial exercises although recommended is not required.

(e) Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants.

(f) The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan.

(g) Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response.

(h) Deficiencies found by the critiques must be corrected.

(13) Hazardous chemicals - a certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-To-Know Act of 1986, Title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

3.9.11.4 The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the Department.

(1) The licensee shall provide any comments received within 60 days to the Department with the emergency plan.

3.10 Additional Requirements for Issuance of Specific Licenses for Use of Unsealed Radioactive Material.

3.10.1 In addition to the requirements set forth in 3.9, applicants for licenses authorizing the possession and use of unsealed radioactive materials shall include in the application a description of the facility and procedures for operation which

3.10.1.1 Minimize to the extent practicable, contamination of the facility and environment;

3.10.1.2 Facilitate eventual decommissioning; and

3.10.1.3 Minimize, to the extent practicable, the generation of radioactive waste.

3.10.2 Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in Part 4, Section 4.5 and radiological criteria for license termination in Part 4, Section 4.61 of the regulations.

3.11 Special Requirements for Specific Licenses of Broad Scope.

3.11.1 This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing holders of the types of broad licenses set forth below. [7]

7 Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

3.11.1.1 A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose.

(1) The quantities specified are usually in the multicurie range.

3.11.1.2 A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, possession, use and transfer of any chemical or physical form of radioactive material specified in Schedule 3D of this part, for any authorized purpose.

(1) The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Schedule 3D, Column I.

(2) If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Schedule 3D, Column I, for that radionuclide.

(3) The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

3.11.1.3 A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in Schedule 3D of this part, for any authorized purpose.

(1) The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Schedule 3D, Column II.

(2) If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Schedule 3D, Column II, for that radionuclide.

(3) The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

3.11.2 An application for a Type A specific license of broad scope will be approved if:

3.11.2.1 The applicant satisfies the general requirements specified in 3.9;

3.11.2.2 The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

3.11.2.3 The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(1) The establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

(2) The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(3) The establishment of appropriate administrative procedures to assure:

(a) Control of procurement and use of radioactive material;

(b) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, the operating or handling procedures; and

(c) Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 3.11.2.3(3)(b) prior to use of the radioactive material.

3.11.3 An application for a Type B specific license of broad scope will be approved if:

3.11.3.1 The applicant satisfies the general requirements specified in 3.9; and

3.11.3.2 The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(1) The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(2) The establishment of appropriate administrative procedures to assure;

(a) Control of procurement and use of radioactive material;

(b) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(c) Review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with 3.11.3.2(2)(b) prior to use of the radioactive material.

3.11.4 An application for a Type C specific license of broad scope will be approved if:

3.11.4.1 The applicant satisfies the general requirements specified in 3.9;

3.11.4.2 The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

(1) A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering, and

(2) At least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

3.11.4.3 The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

3.11.5 Specific licenses of broad scope are subject to the following conditions:

3.11.5.1 Unless specifically authorized, persons licensed pursuant to 3.11 shall not:

(1) Conduct tracer studies in the environment involving direct release of radioactive material;

(2) Receive, acquire, own, possess, use; or transfer devices containing 3.7 PBq (100 kCi) or more of radioactive material in sealed sources used for irradiation of materials;

(3) Conduct activities for which a specific license issued by the Department under 3.10, 3.12, or Parts 7, 14, and 18 is required; or

(4) Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

3.11.5.2 Each Type A specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

3.11.5.3 Each Type B specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

3.11.5.4 Each Type C specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of 3.11.4.

3.12 Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices which Contain Radioactive Material.

3.12.1 A licensee authorized to introduce radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under 3.3.1.1 shall meet the requirements of 10 CFR 32.11 and any other applicable NRC requirement.

3.12.2 No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempted pursuant to 3.3.2, under 10 CFR 30.14 or equivalent regulations of an Agreement State, except in accordance with a license issued under 10 CFR 32. [8]

8 Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

3.12.2.3 Each person licensed under 3.12.2 shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under 3.3.2, 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 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to 3.12.2 during the reporting period, the report shall so indicate.

3.12.3 **RESERVED.**

3.12.4 Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under 3.6.4.

3.12.4.1 An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 3.6.4 or equivalent regulations of NRC or an Agreement State will be approved if:

(1) The applicant satisfies the general requirements of 3.9;

(2) 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 percent of the limits specified in 4.6.1; 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 radiation dose or dose commitment in excess of the following organ doses:

(i) Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye: 150 mSv (15 rem)

(ii) Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter: 2 Sv (200 rem)

(iii) Other organs: 500 mSv (50 rem); and

(3) 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 one 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. ___ [9] , are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

_____

Name of manufacturer or distributor

9 The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

(ii) The receipt, possession, use, and transfer of this device, Model___, Serial No. ___ [10] , are subject to a general license or the equivalent, and the radiation regulations. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

_____

Name of manufacturer or distributor

10 The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

(4) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution-Radioactive Material," the radiation symbol prescribed in 4.27 and the name of the manufacturer or initial distributor.

3.12.4.2 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, the applicant shall include in the 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.

3.12.4.3 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:

(1) Primary containment or source capsule;

(2) Protection of primary containment;

(3) Method of sealing containment;

(4) Containment construction materials;

(5) Form of contained radioactive material;

(6) Maximum temperature withstood during prototype tests;

(7) Maximum pressure withstood during prototype tests;

(8) Maximum quantity of contained radioactive material;

(9) Radiotoxicity of contained radioactive material; and

(10) Operating experience with identical devices or similarly designed and constructed devices.

3.12.4.4 In the event the applicant desires that the general licensee under 3.6.4, or under equivalent regulations of NRC or an Agreement 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, the applicant shall include in the 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.

(1) 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 percent of the limits specified in 4.6.1.

3.12.4.5 Each person licensed under 3.12.4 to distribute devices to generally licensed persons shall:

(1) Before a device is transferred, furnish information specified in this paragraph to each person to whom a device is to be transferred, or in the case of a transfer through an intermediate person, to the intended user prior to initial transfer to the intermediate person, including:

(a) A copy of the general license contained in 3.6.4 and a copy of the general license contained in the NRC or Agreement State regulation equivalent to 3.6.4;

(b) A copy of sections 3.6 and 4.40 through 4.52;

(c) A list of the services that can only be performed by a specific licensee;

(d) Information on acceptable disposal options including estimated costs of disposal;

(e) An indication that federal policy is to issue high civil penalties for improper disposal; and

(f) The name or title, address, and phone number of the contact at the transferee’s NRC or Agreement State location.

(2) Report to the Department all transfers of such devices to persons for use under the general license in 3.6.4 and all receipts of such devices.

(a) Such a report to the Department shall include:

(i) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;

(ii) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(iii) The date of transfer;

(iv) The type, model number, and serial number of the device transferred; and

(v) The quantity and type of radioactive material contained in the device.

(b) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(c) For devices received from a 3.6.4 general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(d) If the licensee makes changes to a device possessed by a 3.6.4 general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(e) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(f) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(g) If no transfers have been made to or from persons generally licensed under 3.6.4 during the reporting period, the report must so indicate.

(3) Furnish clear and legible reports to other agencies, containing all of the data required by Form 653, "Transfers of Industrial Devices Report", including:

(a) Report the information specified in 3.12.4.5(2) to NRC for all transfers of such devices to persons for use under NRC general license in Section 31.5 of 10 CFR Part 31 (January 1, 2013).

(b) Report the information specified in 3.12.4.5 (2) to the responsible State agency for all transfers of devices manufactured and distributed pursuant to 3.12.4 for use under a general license in that State's regulations equivalent to 3.6.4.

(4) Maintain all information concerning transfers and receipts of devices that supports the reports required by this section for a period of 3 years following the date of the recorded event.

3.12.5 Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft.

3.12.5.1 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 3.6.5 will be approved if:

(1) The applicant satisfies the general requirements specified in 3.9; and

(2) The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, 32.56, and 32.101 of 10 CFR Part 32 (January 1, 2013), or their equivalent.

3.12.6 Special Requirements for License to Manufacture Calibration Sources Containing Americium–241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed Under 3.6.7.

3.12.6.1 An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under 3.6.7 will be approved if:

(1) The applicant satisfies the general requirement of 3.9; and

(2) The applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 (January 1, 2013) or their equivalent.

3.12.7 Reserved.

3.12.8 Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License.

3.12.8.1 An application for a specific license to manufacture or distribute radioactive material for use under the general license of 3.6.9 will be approved if:

(1) The applicant satisfies the general requirements specified in 3.9.

(2) The radioactive material is to be prepared for distribution in prepackaged units of:

(a) Carbon-14 in units not exceeding 370 kBq (10 µCi) each.

(b) Cobalt-57 in units not exceeding 370 kBq (10 µCi) each.

(c) Hydrogen-3 (tritium) in units not exceeding 1.85 MBq (50 µCi) each.

(d) Iodine-125 in units not exceeding 370 kBq (10 µCi) each.

(e) Mock Iodine-125 in units not exceeding 1.85 kBq (0.05 µCi) of iodine-129 and 185 kBq (0.005 µCi) of americium-241 each.

(f) Iodine-131 in units not exceeding 370 kBq (10 µCi) each.

(g) Iron-59 in units not exceeding 740 kBq (20 µCi) each.

(h) Selenium-75 in units not exceeding 370 kBq (10 µCi) each.

(3) Each prepackaged unit bears a durable, clearly visible label:

(a) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 370 kBq

(10 µCi) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 1.85 MBq (50 µCi) of hydrogen-3 (tritium); 740 kBq (20 µCi) of iron-59; or Mock Iodine-125 in units not exceeding 1.85 kBq (0.05 µCi) of iodine-129 and 185 Bq (0.005 µCi) of americium-241 each; and

(b) Displaying the radiation caution symbol described in 4.27.1and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".

(4) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one 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 may be received, acquired, possessed, and used only by physicians, veterinarians, 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 NRC or an Agreement State.

_____

Name of manufacturer

(5) 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 4.33.

3.12.9 Licensing the Manufacture and Distribution of Ice Detection Devices.

3.12.9.1 An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under 3.6.10 will be approved if:

(1) The applicant satisfies the general requirements of 3.9; and

(2) The criteria of Sections 32.61, 32.62, and 32.103 of 10 CFR Part 32 (January 1, 2013) are met.

3.12.10 Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs for Medical Use.

3.12.10.1 An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs for medical use pursuant to Part 7 will be approved if:

(1) The applicant satisfies the general requirements specified in 3.9;

(2) The applicant submits evidence that the applicant is at least one of the following:

(a) Registered or licensed with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

(b) Registered or licensed with the State Board of Pharmacy as a drug manufacturer;

(c) Licensed as a pharmacy by the State Board of Pharmacy;

(d) Operating as a nuclear pharmacy within a Federal medical institution; or

(e) A Positron Emission Tomography (PET) drug production facility registered with the State Board of Pharmacy.

(3) The applicant submits information on the radionuclide, chemical and physical form, the maximum activity per vial, syringe, generator, or other container of the radioactive drug, and the shielding provided by the packaging of the radioactive material to show it is appropriate for safe handling and storage of radioactive drugs by medical use licensees; and

(4) The applicant has procedures to assure the following labeling requirements:

(a) A label shall be affixed to each transport radiation shield (whether it is constructed of lead, glass, plastic, or other material) of a radioactive drug to be transferred for commercial distribution.

(i) The label shall include the radiation symbol prescribed in 4.27 and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time.

(ii) For radioactive drugs with a half-life greater than 100 days, the time may be omitted.

(b) A label shall be affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution and shall include:

(i) The radiation symbol prescribed in 4.27 and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; and

(ii) An identifier that ensures that the syringe, vial or other container can be correlated with the information on the transport radiation shield label.

3.12.10.2 A radioactive materials licensee who is also licensed by the State Board of Pharmacy:

(1) May prepare radioactive drugs for medical use, as defined in 1.2 and Part 7, provided that the radioactive drug is prepared by either:

(a) An authorized nuclear pharmacist, as specified in 3.12.10.2(2) or 3.12.10.2(4), or

(b) An individual under the direct supervision of an authorized nuclear pharmacist as specified in 7.10;

(2) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(a) This individual qualifies as an Authorized Nuclear Pharmacist as defined in 7.2;

(b) This individual meets the requirements specified in Part 7, Appendix 7C, and the licensee has received a Department license amendment identifying this individual as an authorized nuclear pharmacist; or

(c) This individual is designated as an authorized nuclear pharmacist in accordance with 3.12.10.2(4).

(3) The actions authorized in 3.12.10.2(1) and 3.12.10.2(2) are permitted in spite of more restrictive language in license conditions.

(4) May designate a pharmacist (as defined in 7.2) as an authorized nuclear pharmacist if:

(a) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and

(b) The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

(5) Shall provide to the Department a copy of each individual's:

(a) Certification by a specialty board whose certification process has been recognized by the NRC or an Agreement State as specified in Part 7, Appendix 7C with the written attestation signed by a preceptor as required by Part 7, Appendix 7C, Section 7C2.2; or

(b) Department, NRC or Agreement State license that allows such work, or

(c) NRC master materials licensee permit, or

(d) The permit issued by a licensee or NRC master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or

(e) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

(f) A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under 3.12.10.2(2)(a) and

3.12.10.2(2)(c), the individual to work as an authorized nuclear pharmacist.

3.12.10.3 A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs.

(1) The licensee shall have procedures for use of the instrumentation.

(2) The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta- or photon-emitting radioactive drugs prior to transfer for commercial distribution.

(3) In addition, the licensee shall:

(a) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(b) Check each instrument for constancy and proper operation at the beginning of each day of use.

3.12.10.4 Nothing in this section relieves the licensee from complying with applicable FDA, Federal, and state requirements governing radioactive drugs.

3.12.11 Reserved.

3.12.12 Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use.

3.12.12.1 An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Part 7 for use as a calibration, transmission, or reference source or for the uses listed in 7.19, 7.40, 7.42, 7.48 and 7.62 will be approved if:

(1) The applicant satisfies the general requirements in 3.9 of this part;

(2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(a) The radioactive material contained, its chemical and physical form, and amount,

(b) Details of design and construction of the source or device,

(c) 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,

(d) For devices containing radioactive material, the radiation profile of a prototype device,

(e) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,

(f) Procedures and standards for calibrating sources and devices,

(g) Legend and methods for labeling sources and devices as to their radioactive content, and

(h) 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;

(3) 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 source or device is licensed by the Department for distribution to persons licensed pursuant to 7.40 and 7.42 or under equivalent licenses of NRC or an Agreement State, provided that such labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source;

3.12.12.2 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, the applicant shall include in the 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; and

3.12.12.3 In determining the acceptable interval for test of leakage of radioactive material, the Department will consider information that includes, but is not limited to:

(1) Primary containment or source capsule,

(2) Protection of primary containment,

(3) Method of sealing containment,

(4) Containment construction materials,

(5) Form of contained radioactive material,

(6) Maximum temperature withstood during prototype tests,

(7) Maximum pressure withstood during prototype tests,

(8) Maximum quantity of contained radioactive material,

(9) Radiotoxicity of contained radioactive material, and

(10) Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

3.12.13 Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications.

3.12.13.1 An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 3.5.5 or equivalent regulations of NRC or an Agreement State will be approved if:

(1) The applicant satisfies the general requirements specified in 3.9;

(2) 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 percent of the limits specified in 4.6.1; and

(3) 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.

3.12.13.2 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 3.12.13 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.

3.12.13.3 The Department may deny any application for a specific license under 3.12.13 if the end use(s) of the industrial product or device cannot be reasonably foreseen.

3.12.13.4 Each person licensed pursuant to 3.12.13.1 shall:

(1) 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;

(2) 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 NRC or an Agreement State;

(3) 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";

(4) Furnish a copy of the general license:

(a) Contained in 3.5.5 and a copy of Department Form R-52 to each person to whom the specific licensee transfers depleted uranium in a product or device for use pursuant to the general license contained in 3.5.5, or

(b) Contained in an NRC or Agreement State regulation equivalent to 3.5.5 and a copy of an NRC or Agreement State certificate, or alternatively, furnish a copy of the general license contained in 3.5.5 and a copy of Department Form R-52 to each person to whom the specific licensee transfers depleted uranium in a product or device for use pursuant to the general license of NRC or an Agreement State, with a note explaining that use of the product or device is regulated by NRC or an Agreement State under requirements substantially the same as those in 3.5.5;

(5) Report to the Department all transfers of industrial products or devices to persons for use under the general license in 3.5.5.

(a) 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.

(b) 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.

(c) If no transfers have been made to persons generally licensed under 3.5.5 during the reporting period, the report shall so indicate;

(6) Report to NRC all transfers of industrial products or devices to persons for use under NRC general license in Section 40.25 of 10 CFR Part 40 (January 1, 2010).

(a) 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 device transferred, and the quantity of depleted uranium contained in the product or device.

(b) 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.

(c) If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to NRC;

(7) Report to the responsible State agency all transfers of devices manufactured and distributed pursuant to 3.12.13 for use under a general license in that State's regulations equivalent to 3.5.5,

(a) 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 device transferred, and the quantity of depleted uranium contained in the product or device.

(b) 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.

(c) If no transfers have been made general licensees within a particular agreement state during the reporting period, this information shall be reported to the responsible Agreement State agency upon the request of that agency;

(8) Keep records showing the name, address, and point of contact for each general licensee to whom the specific licensee transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 3.5.5 or equivalent regulations of NRC or an Agreement State.

(a) 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 section.

3.12.14 Registration of Product Information.

3.12.14.1 Any manufacturer or initial distributor of a sealed source, or of a device containing a sealed source, whose product is intended for use under a specific license may submit a request to the Department for evaluation of radiation safety information about the product and for the product registration.

3.12.14.2 The request for review must be made in duplicate and sent to the Director, Hazardous Materials And Waste Management Division, Colorado Department of Public Health and Environment, 4300 Cherry Creek Drive South, Denver, Colorado 80246-1530.

3.12.14.3 The request for review of a sealed source or device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

3.12.14.4 The Department normally evaluates a sealed source or device using radiation safety criteria in accepted industry standards.

(1) If these standards and criteria do not readily apply to a particular case, the Department formulates reasonable standards and criteria with the help of the manufacturer or distributor.

(2) The Department shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.

3.12.14.5 After completion of the evaluation, the Department issues a certificate of registration to the person making the request. The certificate of registration

acknowledges the availability of the submitted information for inclusion in an application for specific license proposing use of the product.

3.12.14.6 The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:

(1) The statements and representations, including quality control program, contained in the request; and

(2) The provisions of the certificate of registration.

3.13 Third-Party Method.

3.13.1 If the applicant consents, the Department may enter into third party agreements for the applicant to engage and pay for the services of a third party contractor to prepare the environmental impact analysis required under 18.4 and/or to furnish an opinion of independent experts, satisfactory to the Department, in respect to the completeness and adequacy of any information or data furnished by the applicant and on any aspect of the applicant's project or effects thereof.

3.13.2 In proceeding under the third party agreement, the Department shall carry out the following practices:

3.13.2.1 Such contractor shall be chosen solely by the Department.

3.13.2.2 The Department shall manage the contract.

3.13.2.3 The consultant shall be selected based on the consultant's ability relevant and applicable work experience and an absence of conflict of interest. Third party contractors will be required to execute a disclosure statement signifying they have no financial or other conflicting interest in the outcome of the project.

3.13.2.4 The Department shall specify the information to be developed and supervise the gathering, analysis and presentation of the information.

3.13.2.5 The Department shall have sole authority for approval and modification of the statement, analysis, and conclusions included in third party's report.

3.13.3 When the license applicant pays for a third party agreement, the monies paid for the consultant shall not be charged as part of the fees required under Part 12.

3.14 Issuance of a Specific License.

3.14.1 Upon a determination that an application meets the requirements of the Act and the regulations of the Department, the Department will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

3.14.2 The Department may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this part, as it deems appropriate or necessary in order to:

3.14.2.1 Minimize danger to public health and safety or property;

3.14.2.2 Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

3.14.2.3 Prevent loss or theft of material subject to this part.

3.14.3 Whenever the Department denies an application for a new license or a license renewal, the Department will notify the applicant in writing stating the grounds for denial

3.14.3.1 Upon denial, the applicant may request a hearing pursuant to Sections 24-4-104 and 24-4-105, CRS.

3.15 Specific Terms and Conditions of License.

3.15.1 Each license issued pursuant to this part shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Department.

3.15.2 Inalienability of Licenses.

3.15.2.1 No license issued or granted under this part and no right to possess or utilize radioactive material granted by any license issued pursuant to this part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Department shall, after securing full information, find that the transfer is in accordance with the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations, and orders of the Department, and shall give its consent in writing.

3.15.2.2 An application for transfer of license must include:

(1) The identity, technical and financial qualifications of the proposed transferee;

(2) Financial assurance for decommissioning information required by 3.9.6;

(3) A description of the acquisition or proposed transfer including dates;

(4) An updated organizational chart including the proposed transferee’s management structure for the licensed activities;

(5) Documentation of registration with the Colorado Secretary of State for the proposed transferee;

(6) A statement from the proposed transferee's management that they will conduct business in accord with all of the commitments previously submitted by the current licensee;

(7) A statement from the proposed transferee's management accepting liability for all licensed materials that are and have been possessed under the license; and

(8) A copy of the appropriate radioactive materials license application signed by the RSO and the proposed transferee's management.

3.15.3 Each person licensed by the Department pursuant to this part shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

3.15.4 Notice and Disposition of Records Prior to License Termination.

3.15.4.1 Each licensee shall notify the Department in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

3.15.4.2 Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the Department.

(1) Records of disposal required by 4.48; and

(2) Records of surveys required by 4.42.

3.15.4.3 If licensed activities are transferred or assigned in accordance with 3.15.2, each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the records required in 3.15.4.2 to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated.

3.15.4.4 Prior to license termination, each licensee shall forward the records required by 3.16.5 to the Department.

3.15.5 Bankruptcy.

3.15.5.1 Each specific licensee and each general license that is required to register by 3.6.4.3 of this part shall notify the Department in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(1) The licensee;

(2) An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

(3) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

3.15.5.2 The notification specified in 3.15.5.1 shall include the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

3.15.6 Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with Part 7. The licensee shall record the results of each test and retain each record for 3 years after the record is made.

3.15.7 Authorization under 3.8.10 to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

3.15.7.1 Each licensee authorized under 3.8.10 to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(1) Satisfy the labeling requirements in 3.12.10.1(4) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(2) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in 3.12.10.3.

3.15.7.2 A licensee that is a pharmacy authorized under 3.8.10 to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(1) An authorized nuclear pharmacist that meets the requirements in 3.12.10.2(2),

or

(2) An individual under the supervision of an authorized nuclear pharmacist as specified in Part 7, Section 7.10.

3.15.7.3 A pharmacy, authorized under 3.8.10 to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of 3.12.10.2(5).

3.16 Expiration, Decommissioning and Termination of Licenses.

3.16.1 Definition of "principal activity".

3.16.1.1 As used in this regulation, "principal activity" means an activity authorized by the license which is essential to achieving the purpose(s) for which the license was issued or amended.

3.16.1.2 Not included as principal activities are:

(1) Radioactive material storage while no licensed material is accessed for use or disposal; and

(2) Any activity incidental to decontamination or decommissioning.

3.16.2 Expiration.

3.16.2.1 Except as provided in 3.17.2, each specific license shall expire at the end of the specified day in the month and year stated therein.

3.16.2.2 Each specific license revoked by the Department expires at the end of the day on the date of final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by order.

3.16.2.3 With respect to possession of radioactive material and residual radioactive contamination, each specific license continues in effect beyond the expiration date until the Department notifies the licensee in writing that the license is terminated, even if:

(1) The licensee decides not to renew the license;

(2) No application for license renewal is submitted;

(3) An application for renewal is denied; or

(4) The Department modifies or suspends a license.

3.16.2.4 No less than 30 days before the expiration date specified in the license, the licensee shall either:

(1) Submit an application for license renewal under 3.17; or

(2) Notify the Department, in writing, that the licensee has decided not to renew the license.

3.16.2.5 If a licensee does not submit an application for license renewal under 3.17, the licensee shall, on or before the expiration date specified in the license:

(1) Terminate use of radioactive material;

(2) Transfer radioactive materials to an authorized recipient and/or properly dispose of radioactive material;

(3) Reduce residual radioactive contamination to levels which are as low as reasonably achievable (ALARA); and

(4) Submit a completed Department Form R-23, *Request for Termination of a Radioactive Materials License* , or equivalent information requesting license termination, including survey results, leak tests, disposal records, and/or other documentation which demonstrates acceptable conditions for license termination as specified in 3.16.6.

3.16.2.6 Each licensee who possesses radioactive material, including residual radioactive contamination attributable to licensed activities, following the expiration date specified in the license shall:

(1) Limit actions involving radioactive material to those related to decontamination and other activities related to preparation for release for unrestricted use; and

(2) Continue to control entry to restricted areas until they are suitable for release for unrestricted use or the Department notifies the licensee in writing that the license is terminated.

3.16.2.7 Each licensee or person responsible for a facility or site which includes a non-exempt source of radiation or which may be contaminated by residual radioactivity shall, no less than 30 days before vacating or relinquishing possession or control of the facility or site, notify the agency, in writing, of the intent to vacate.

3.16.3 Timely Decommissioning.

3.16.3.1 Each licensee or person in possession of a non-exempt source of radiation who decides to terminate all activities involving that source of radiation shall notify the hazardous materials and waste management division immediately, in writing.

3.16.3.2 The licensee shall notify the Hazardous Materials And Waste Management Division in writing within 60 days of the occurrence of any of the following:

(1) The licensee has decided to permanently cease principal activities, as defined in this part, at the entire site or in any separate building or outdoor area that

contains residual radioactivity such that the building or outdoor area is unsuitable for unrestricted use in accordance with 4.61; or

(2) No principal activities under the license have been conducted for a period of 24 months; or

(3) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for unrestricted use in accordance with these regulations.

3.16.3.3 Concurrent with the notification of the Hazardous Materials And Waste Management Division required in 3.16.3.1 and 3.16.3.2, the licensee shall either:

(1) Begin decommissioning activities; or,

(2) Within 12 months of notification, submit a decommissioning plan if required by 3.16.4, and begin decommissioning upon approval of that plan.

3.16.3.4 Licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning, unless an alternate schedule addressing the factors in 3.16.4 is requested and approved by the Department.

3.16.3.5 When decommissioning involves the entire site, the licensee shall request license termination upon completion of decommissioning activities.

3.16.3.6 The Department may approve alternate schedules for the submission of plans and for the completion of decommissioning as required pursuant to 3.16.3.3 and 3.16.3.4 if the Department determines that the alternate schedule:

(1) Is necessary to effectively conduct decommissioning;

(2) Presents no undue risks to public health and safety; and

(3) Is otherwise in the public interest.

3.16.4 Decommissioning Plan.

3.16.4.1 A licensee must submit a decommissioning plan:

(1) If the licensee intends to terminate the license using radiological criteria specified in 4.61.3 or 4.61.4 (the exemption of 4.61.1.1 applies);

(2) If required otherwise by these regulations;

(3) If required by license condition; or

(4) If the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Department and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(a) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(b) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(c) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(d) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

3.16.4.2 Procedures such as those listed in 3.16.4.1 of this section with potential health and safety impacts may not be carried out prior to Department approval of the decommissioning plan.

3.16.4.3 The decommissioning plan for the site or separate building or outdoor area must include:

(1) A description of the conditions of the site, separate buildings, and/or outdoor areas sufficient to evaluate the acceptability of the plan;

(2) A description of planned decommissioning activities and a schedule for completion;

(3) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(4) A description of the planned final radiation survey;

(5) A current detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning; and

(6) A description of the intended final condition of the site, separate buildings, and/or outdoor areas upon completion of decommissioning activities.

(7) Decommissioning plans proposing the use of radiological criteria specified in 4.61.3 or 4.61.4, must also include:

(a) An analysis demonstrating that reductions in residual radioactivity necessary to comply with the provisions of 4.61.2 would result in net public or environmental harm or were not being made because the residual levels of contamination associated with restricted conditions are ALARA.

(i) Determination of dose and residual radioactivity levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal;

(b) A description of the institutional controls necessary to satisfy the requirements of 4.61.3.2, including a description of how the controls will be enforced and an analysis showing that the controls will not impose undue burdens on the local community or other affected parties;

(c) An analysis demonstrating that if institutional controls were no longer in effect then the dose criteria of 4.61.3.4 will be met;

(d) A detailed cost estimate for a long-term care warranty, and a plan for establishing a Department approved warranty prior to completion of decommissioning activities;

(e) A description of how the licensee will seek advice from representatives of a broad cross section of community interests who may be affected by the decommissioning and how the licensee will provide participants an opportunity for a comprehensive, collective discussion on key decommissioning issues, including: the adequacy and enforceability of institutional controls, burdens/impacts to local communities and affected parties, and the adequacy of financial assurance; and

(f) A description of how the licensee will make publicly available a summary of the results of all such discussions, including: a description of the individual viewpoints of the participants on the issues, the extent of agreement and disagreement among the participants on the issues, and a description of how key issues in disagreement will be addressed during decommissioning.

3.16.4.4 For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the decommissioning schedule which addresses the following:

(1) Whether it is technically feasible to complete decommissioning within a 24-month period;

(2) Whether sufficient waste disposal capacity is available to allow completion of decommissioning with a 24-month period;

(3) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(4) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(5) Other site-specific factors which the Department may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

3.16.4.5 Upon the receipt of a decommissioning plan or proposal by the licensee for release of a site pursuant to 4.61.3 or 4.61.4, or whenever the Department deems such notice to be in the public interest, the Department shall:

(1) Notify and solicit comments from:

(a) Local and state governments in the vicinity of the site and any Indian nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and

(b) The environmental protection agency for cases where the licensee proposes to release a site pursuant to 4.61.4.

(2) Publish a notice in a forum, such as local newspapers, letters to state or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

3.16.4.6 The proposed decommissioning plan will be approved by the Department if the information therein demonstrates that the decommissioning will be in accordance with the requirements of 3.9.5.10, 3.16, and 4.61 (the exemption of 4.61.1.1 applies), completed as soon as practicable, and that the health and safety of workers and the public will be adequately protected.

3.16.5 Decommissioning Record Keeping.

3.16.5.1 The licensee shall keep records of information important to the decommissioning of a facility in an identified location until authorized by the Department.

(1) Before licensed activities are transferred or assigned in accordance with 3.15.2, licensees shall transfer all records described in this paragraph to the new licensee.

(2) In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used.

3.16.5.2 Information considered important to decommissioning includes:

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site.

(a) These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete.

(b) These records must include any known information on identification of involved nuclides, quantities, forms and concentrations.

(2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination.

(a) If required drawings are referenced, each relevant document needs to be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(3) A list contained in a single document and updated every 2 years -- except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak), radioactive materials having only half-lives of less than 65 days, or areas containing depleted uranium used only for shielding or as penetrators in unused munitions, -- of the following:

(a) All areas designated and formerly designated restricted areas as defined in 1.4;

(b) All areas outside of restricted areas that require documentation under 3.16.5.2(1);

(c) All areas outside of restricted areas where current and previous wastes have been buried as documented under 4.48; and

(d) All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal under 4.34.

(e) A list containing the location and description of all equipment to remain onsite after license termination that was contaminated when final decommissioning was initiated; and

(f) Any other information not required by 3.16.5.3 that is considered necessary to support the adequacy of the decommissioning plan for approval.

(4) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

(5) For licenses decommissioned in accordance with the requirements of 4.61.3 or 4.61.4, the licensee shall maintain documentation of public meetings held to discuss decommissioning activities.

(a) This documentation is to include the dates and locations of the meetings, participants, topics of discussion, a description of the individual viewpoints of the participants on the issues, the extent of agreement and disagreement among the participants on the issues, and a description of how key issues in disagreement were addressed during decommissioning.

3.16.6 Demonstrating Acceptable Conditions for License Termination.

3.16.6.1 The Department will address comments provided by the U.S. Environmental Protection Agency and public comments submitted pursuant to 3.16.4.5 prior to the use of the alternate criteria, authorized in 4.61.4, to terminate a license.

3.16.6.2 The licensee shall conduct a radiation survey of the licensee's site to confirm the absence of radioactive material and/or to establish levels of residual radioactive contamination, unless the licensee can demonstrate that the site is suitable for release in some other manner.

(1) As appropriate, the licensee shall also conduct radiation surveys in any separate building or outdoor area that contains residual radioactivity resulting from the licensee's activities.

3.16.6.3 The licensee shall submit a report of the results of this survey and/or other documentation to the Department which demonstrates compliance with the radiological criteria for license termination specified in Part 4 of the regulations.

3.16.6.4 The licensee's report required by 16.6.6.3 shall specify, as appropriate:

(1) Levels of gamma radiation in units of microsievert per hour (μSv/hr or μrem/ hr) at one meter from surfaces;

(2) Levels of radioactive surface contamination, including alpha and beta emitting radioactive materials, in units of disintegrations per minute per 100 square centimeters (dpm/100cm ^{2} or Bq/100cm ^{2}), specifying levels for both removable and fixed contamination;

(3) Levels of radioactivity in units of becquerel per liter (Bq/l or pCi/l) for water, and becquerel per gram (Bq/g or pCi/g) for solids such as soils or concrete; and

(4) Survey instrument(s) used including certification that each instrument is properly calibrated and tested.

3.16.7 License Termination.

3.16.7.1 Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Department determines that:

(1) Radioactive materials have been properly disposed and records of disposal required by 4.48 to be maintained and retained have been forwarded to the Department as required by 3.15.4;

(2) The licensee has demonstrated, by radiation survey results and/or other appropriate methods, that the license termination will be in compliance with these regulations;

(3) The licensee has established a Department approved long term care warranty, if required;

(4) Department approved institutional controls have been implemented to limit public doses, if required; and

(5) All records required by 3.16.5 have been transferred to the Department.

3.16.8 Additional Cleanup.

3.16.8.1 Except for facilities exempted under 4.61.1.1, after a site has been decommissioned and the license terminated in accordance with 3.16 and 4.61, the Department may reinstate the terminated license or issue a new license and require additional cleanup only if, based on new or previously unknown information, it determines that the criteria of 4.61 were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

3.17 Renewal of Licenses.

3.17.1 Applications for renewal of specific licenses shall be filed in accordance with 3.8.

3.17.2 In any case in which a licensee, not less than 30 days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the Department.

3.18 Amendment of Licenses at Request of Licensee.

3.18.1 Applications for amendment of a license shall be filed in accordance with 3.8 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

3.19 Agency Action on Applications to Renew and Amend.

3.19.1 In considering an application by a licensee to renew or amend the license, the Department will apply the criteria set forth in 3.9 and 3.10, 3.11, 3.12, and in Parts 5, 7, 14, 16, 18 and 19, as applicable.

3.20 Reserved.

3.21 Reserved.

TRANSFER OF MATERIALS

3.22 Transfer of Material.

3.22.1 No licensee shall transfer radioactive material except as authorized pursuant to 3.22.

3.22.2 Except as otherwise provided in his license and subject to the provisions of 3.22.3 and 3.22.4, any licensee may transfer radioactive material:

3.22.2.1 To the Department [10] ;

10 A licensee may transfer material to the Department only after receiving prior approval from the Department.

3.22.2.2 To the U.S. Department of Energy;

3.22.2.3 To any person exempt from the regulations in this part to the extent permitted under such exemption;

3.22.2.4 To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Department, NRC or any Agreement State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Department, or an Agreement State;

3.22.2.5 To any person abroad pursuant to an export license granted by NRC under 10 CFR Part 110; or

3.22.2.6 As otherwise authorized by the Department in writing.

3.22.3 Before transferring radioactive material to a specific licensee of the Department, NRC or an Agreement State, or to a general licensee who is required to register with the Department, NRC or an Agreement State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

3.22.4 Any of the following methods for the verification required by 3.22.3 is acceptable:

3.22.4.1 The transferor may possess and read a current copy of the transferee's specific license or registration certificate.

3.22.4.2 The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and

quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date.

3.22.4.3 For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within 10 days.

3.22.4.4 The transferor may obtain other information compiled by a reporting service from official records of the Department, NRC or an Agreement State regarding the identity of licensees and the scope and expiration dates of licenses and registration.

3.22.4.5 When none of the methods of verification described in 3.22.4.1 through 3.22.4.4 are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Department, NRC, or an Agreement State that the transferee is licensed to receive the radioactive material.

3.22.5 Shipment and transport of radioactive material shall be in accordance with the provisions of Part 17.

MODIFICATION AND REVOCATION OF LICENSES

3.23 Modification and Revocation of Licenses.

3.23.1 The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act, or by reason of rules, regulations, and orders issued by the Department.

3.23.2 Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Department to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule, regulation, or order of the Department.

3.23.3 Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

RECIPROCITY

3.24 Reciprocal Recognition of Licenses.

3.24.1 Radioactive Material in Quantities Not Sufficient to Form a Critical Mass.

3.24.1.1 Subject to these regulations, any person who holds a specific license from NRC or an Agreement State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State for a period not in excess of 180 days in any calendar year, provided that:

(1) The licensing document does not limit the activity authorized by such document to specified installations or locations;

(2) The out-of-state licensee notifies the Department in writing at least 3 days prior to engaging in such activity.

(a) Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document.

(b) Based upon an application which includes documentation of why it is not possible or is an undue hardship to provide 3 days notice, the Department may grant permission to proceed sooner.

(c) The Department may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in 3.24.1.1;

(3) The out-of-state licensee complies with all applicable regulations of the Department and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Department;

(4) The out-of-state licensee supplies such other information as the Department may request; and

(5) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in 3.24.1.1 except by transfer to a person:

(a) Specifically licensed by the Department, NRC, or an Agreement State, to receive such material; or

(b) Exempt from the requirements for a license for such material under 3.3.1.

(6) The out-of-state licensee shall at all times during work at any work location within the state have available:

(a) The pertinent licensing document;

(b) The applicable sections of the state radiation regulations;

(c) A complete source inventory;

(d) Pertinent DOT documentation;

(e) Leak test records;

(f) Instrument calibration records;

(g) Personnel training records; and

(h) Necessary documentation required by applicable special requirements of these regulations.

(7) While working in Colorado, the out-of-state licensee shall notify the Department (in writing, indicating date and court) immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States code by or against:

(a) The licensee;

(b) An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

(c) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the license.

(8) The out-of-state licensee shall notify the Department within 1 hour after arrival at the actual work location within the state and notification within 1 hour after any change of work location within the state.

(9) If multiple persons work concurrently at more than one work location under a general license granted pursuant to this 3.24.1, each day worked per location shall be counted separately toward the limit of 180 days per calendar year.

3.24.1.2 Notwithstanding the provisions of 3.24.1.1, any person who holds a specific license issued by NRC or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in 3.6.4.1 within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this State provided that:

(1) Such person shall file a report with the Department within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State.

(a) Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

(2) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by an Agreement State or NRC;

(3) Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of This Label Is Prohibited"; and

(4) The holder of the specific license shall furnish to each general licensee to whom the specific licensee transfers such device or on whose premises the specific licensee installs such device a copy of the general license contained in 3.6.4 or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

3.24.1.3 The Department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by NRC or an Agreement State, or any product distributed pursuant to such licensing document, upon determining that such

action is necessary in order to prevent undue hazard to public health and safety or property.

3.24.2 Each general licensee granted authorization to conduct activities within this state pursuant to 3.24.1 based upon an acceptable licensing document will receive acknowledgment from the Department. This acknowledgment shall be kept at the site of use.

3.24.3 Each general licensee granted authorization to conduct activities within this state pursuant to 3.24.1 based upon an acceptable licensing document may be inspected by the Department and subject to a fee for the inspection. The fee for a routine inspection shall:

3.24.3.1 Be as provided by Part 12; and

3.24.3.2 Shall not be charged more often than once during each calendar year, except that for a licensee authorizing use of material at more than one address, a separate fee will be assessed for inspection of each location. If multiple installations are inspected during a single visit, a single inspection fee will be assessed.

3.24.4 Each general licensee operating within the state under reciprocity in areas of exclusive federal jurisdiction shall comply with the applicable provisions of 10 CFR 150.20 (January 1, 2013).

PART 3, SCHEDULE 3A: EXEMPT CONCENTRATIONS (3.3.1)

Element (atomic number)	**Isotope**	**Column I Gas Concentration [12] µCi/ml**	**Column II Liquid and Solid Concentration [13] µCi/ml**
Antimony (51)	Sb-122		3×10^{-4}
	Sb-124		2×10^{-4}
	Sb-125		1×10^{-3}
Argon (18)	Ar-37	1×10^{-3}	
	Ar-41	4×10^{-7}	
Arsenic (33)	As-73		5×10^{-3}
	As-74		5×10^{-4}
	As-76		2×10^{-4}
	As-77		8×10^{-4}
Barium (56)	Ba-131		2×10^{-3}
	Ba-140		3×10^{-4}
Beryllium (4)	Be-7		2×10^{-2}
Bismuth (83)	Bi-206		4×10^{-4}
Bromine (35)	Br-82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd-109		2×10^{-3}
	Cd-115m		3×10^{-4}
	Cd-115		3×10^{-4}
Calcium (20)	Ca-45		9×10^{-5}
	Ca-47		5×10^{-4}
Carbon (6)	C-14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce-141		9×10^{-4}
	Ce-143		4×10^{-4}

	Ce-144		1×10^{-4}
Cesium (55)	Cs-131		2×10^{-2}
	Cs-134m		6×10^{-2}
	Cs-134		9×10^{-5}
Chlorine (17)	Cl-38	9×10^{-7}	4×10^{-3}
Chromium (24)	Cr-51		2×10^{-2}
Cobalt (27)	Co-57		5×10^{-3}
	Co-58		1×10^{-3}
	Co-60		5×10^{-4}
Copper (29)	Cu-64		3×10^{-3}
Dysprosium (66)	Dy-165		4×10^{-3}
	Dy-166		4×10^{-4}
Erbium (68)	Er-169		9×10^{-4}
	Er-171		1×10^{-3}
Europium (63)	Eu-152 (9.2 h)		6×10^{-4}
	Eu-155		2×10^{-3}
Fluorine (9)	F-18	2×10^{-6}	8×10^{-3}
Gadolinium (64)	Gd-153		2×10^{-3}
	Gd-159		8×10^{-4}
Gallium (31)	Ga-72		4×10^{-4}
Germanium (32)	Ge-71		2×10^{-2}
Gold (79)	Au-196		2×10^{-3}
	Au-198		5×10^{-4}
	Au-199		2×10^{-3}
Hafnium (72)	Hf-181		7×10^{-4}
Hydrogen (1)	H-3	5×10^{-6}	3×10^{-2}
Indium (49)	In-113m		1×10^{-2}
	In-114m		2×10^{-4}
Iodine (53)	I-126	3×10^{-9}	2×10^{-5}
	I-131	3×10^{-9}	2×10^{-5}
	I-132	8×10^{-8}	6×10^{-4}
	I-133	1×10^{-8}	7×10^{-5}
	I-134	2×10^{-7}	1×10^{-3}
Iridium (77)	Ir-190		2×10^{-3}
	Ir-192		4×10^{-4}
	Ir-194		3×10^{-4}
Iron (26)	Fe-55		8×10^{-3}
	Fe-59		6×10^{-4}
Krypton (36)	Kr-85m	1×10^{-6}	
	Kr-85	3×10^{-6}	
Lanthanum (57)	La-140		2×10^{-4}

Lead (82)	Pb-203		4×10^{-3}
Lutetium (71)	Lu-177		1×10^{-3}
Manganese (25)	Mn-52		3×10^{-4}
	Mn-54		1×10^{-3}
	Mn-56		1×10^{-3}
Mercury (80)	Hg-197m		2×10^{-3}
	Hg-197		3×10^{-3}
	Hg-203		2×10^{-4}
Molybdenum (42)	Mo-99		2×10^{-3}
Neodymium (60)	Nd-147		6×10^{-4}
	Nd-149		3×10^{-3}
Nickel (28)	Ni-65		1×10^{-3}
Niobium (Columbium) (41)	Nb-95		1×10^{-3}
	Nb-97		9×10^{-3}
Osmium (76)	Os-185		7×10^{-4}
	Os-191m		3×10^{-2}
	Os-191		2×10^{-3}
	Os-193		6×10^{-4}
Palladium (46)	Pd-103		3×10^{-3}
Phosphorus (15)	P-32		2×10^{-4}
Platinum (78)	Pt-191		1×10^{-3}
	Pt-193m		1×10^{-2}
	Pt-197m		1×10^{-2}
	Pt-197		1×10^{-3}
Potassium (19)	K-42		3×10^{-3}
Praseodymium (59)	Pr-142		3×10^{-4}
	Pr-143		5×10^{-4}
Promethium (61)	Pm-147		2×10^{-3}
	Pm-149		4×10^{-4}
Rhenium (75)	Re-183		6×10^{-3}
	Re-186		9×10^{-4}
	Re-188		6×10^{-4}
Rhodium (45)	Rh-103m		1×10^{-1}
	Rh-105		1×10^{-3}
Rubidium (37)	Rb-86		7×10^{-4}
Ruthenium (44)	Ru-97		4×10^{-3}
	Ru-103		8×10^{-4}
	Ru-105		1×10^{-3}
	Ru-106		1×10^{-4}
Samarium (62)	Sm-153		8×10^{-4}
Scandium (21)	Sc-46		4×10^{-4}

	Sc-47		9×10^{-4}
	Sc-48		3×10^{-4}
Selenium (34)	Se-75		3×10^{-3}
Silicon (14)	Si-31		9×10^{-3}
Silver (47)	Ag-105		1×10^{-3}
	Ag-110m		3×10^{-4}
	Ag-111		4×10^{-4}
Sodium (11)	Na-24		2×10^{-3}
Strontium (38)	Sr-85		1×10^{-3}
	Sr-89		1×10^{-4}
	Sr-91		7×10^{-4}
	Sr-92		7×10^{-4}
Sulfur (16)	S-35	9×10^{-8}	6×10^{-4}
Tantalum (73)	Ta-182		4×10^{-4}
Technetium (43)	Tc-96m		1×10^{-1}
	Tc-96		1×10^{-3}
Tellurium (52)	Te-125m		2×10^{-3}
	Te-127m		6×10^{-4}
	Te-127		3×10^{-3}
	Te-129m		3×10^{-4}
	Te-131m		6×10^{-4}
	Te-132		3×10^{-4}
Terbium (65)	Tb-160		4×10^{-4}
Thallium (81)	Tl-200		4×10^{-3}
	Tl-201		3×10^{-3}
	Tl-202		1×10^{-3}
	Tl-204		1×10^{-3}
Thulium (69)	Tm-170		5×10^{-4}
	Tm-171		5×10^{-3}
Tin (50)	Sn-113		9×10^{-4}
	Sn-125		2×10^{-4}
Tungsten (Wolfram) (74)	W-181		4×10^{-3}
	W-187		7×10^{-4}
Vanadium (23)	V-48		3×10^{-4}
Xenon (54)	Xe-131m	4×10^{-6}	
	Xe-133	3×10^{-6}	
	Xe-135	1×10^{-6}	
Ytterbium (70)	Yb-175		1×10^{-3}
Yttrium (39)	Y-90		2×10^{-4}
	Y-91m		3×10^{-2}
	Y-91		3×10^{-4}

	Y-92		6×10^{-4}
	Y-93		3×10^{-4}
Zinc (30)	Zn-65		1×10^{-3}
	Zn-69m		7×10^{-4}
	Zn-69		2×10^{-2}
Zirconium (40)	Zr-95		6×10^{-4}
	Zr-97		2×10^{-4}
Beta- and/or gamma-emitting radioactive material not listed above with half-life of less than 3 years.		1×10^{-10}	1×10^{-6}

12 Values are given in Column I only for those materials normally used as gases.

13 µCi/g for solids.

Note 1: Many radionuclides transform into other radionuclides. In expressing the concentrations in Schedule 3A, the activity stated is that of the parent radionuclide and takes into account the radioactive decay products.

Note 2: For purposes of Section 3.3 where there is involved a combination of radionuclides, the limit for the combination should be derived as follows:

Determine for each radionuclide in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in Schedule 3A for the specific radionuclide when not in combination. The sum of such ratios may not exceed "1".

Example:

$$\frac{\text{Concentration of Radionuclide A in Product}}{\text{Exempt concentration of Radionuclide A}} + \frac{\text{Concentration of Radionuclide B in Product}}{\text{Exempt concentration of Radionuclide B}} \leq 1$$

Note 3: To convert µCi/ml to SI units of megabecquerels per liter multiply the above values by 37.

Example: Zirconium (40), Zr-97 (2×10^{-4} µCi/ml multiplied by 37 is equivalent to 74×10^{-4} MBq/l)

PART 3, SCHEDULE 3B: EXEMPT QUANTITIES (3.3.2)

Radioactive Material	Microcuries
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100

Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs 137)	10
Chlorine-36 (Cl 36)	10
Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-58 (Co 58)	10
Cobalt-60 (Co 60)	1
Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100
Erbium-169 (Er 169)	100
Erbium-171 (Er 171)	100
Europium-152 (Eu 152) 9.2h	100
Europium-152 (Eu 152) 13 yr	1
Europium-154 (Eu 154)	1
Europium-155 (Eu 155)	10
Fluorine-18 (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-67 (Ga 67)	100
Gallium-72 (Ga 72)	10
Germanium-68 (Ge 68)	10
Germanium-71 (Ge 71)	100
Gold-195 (Au 195)	10
Gold-198 (Au 198)	100
Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	100
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100
Indium-113m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m (In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I 123)	100
Iodine-125 (I 125)	1
Iodine-126 (I 126)	1
Iodine-129 (I 129)	0.1

Iodine-131 (I 131)	1
Iodine-132 (I 132)	10
Iodine-133 (I 133)	1
Iodine-134 (I 134)	10
Iodine-135 (I 135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10
Iron-55 (Fe 55)	100
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100
Krypton-87 (Kr 87)	10
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100
Mercury-203 (Hg 203)	10
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Nd 149)	100
Nickel-59 (Ni 59)	100
Nickel-63 (Ni 63)	10
Nickel-65 (Ni 65)	100
Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 143)	100
Promethium-147 (Pm 147)	10
Promethium-149 (Pm 149)	10
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (103m)	100

Rhodium-105 (105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulphur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131 m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-.201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100

Vanadium-48 (V 48)	10
Xenon-131m (Xe 131 m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10
Yttrium-88 (Y 88)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha-emitting radioactive material	0.1

Note 1 : For purposes of 3.9.5.3(5)(a) and 3.9.5.3(5)(b) where there is involved a combination of radionuclides, the limit for the combination should be derived as follows:

Determine the amount of each radionuclide possessed and 1,000 times the amount in Schedule 3B for each of those radionuclides when not in combination. The sum of the ratios of those quantities may not exceed 1.

Example:

$$\frac{\text{Amount of Radionuclide A possessed}}{1000 \times \text{Schedule 3B quantity for Radionuclide A}} + \frac{\text{Amount of Radionuclide B possessed}}{1000 \times \text{Schedule 3B quantity for Radionuclide B}} \leq 1$$

Note 2: To convert microcuries (μCi) to SI units of kilobecquerels (kBq), multiply the above values by 37.

Example: Zirconium-97 (10 μCi multiplied by 37 is equivalent to 370 kBq).

PART 3, SCHEDULE 3C: EXEMPT ITEMS (3.2.3 AND 3.3.3)

3C Any person is exempt from this part to the extent that such person receives, possesses, uses, or transfers an item listed below:

3C.1 Any quantities of thorium contained in:

3C.1.1 Incandescent gas mantles;

3C.1.2 Vacuum tubes;

3C.1.3 Welding rods;

3C.1.4 Electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium;

3C.1.5 Germicidal lamps, sunlamps, and lamps for outdoors or industrial lighting provided that each lamp does not contain more than 2 grams of thorium;

3C.1.6 Rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these; or

3C.1.7 Personnel neutron dosimeters provided that each dosimeter does not contain more than 50 milligrams of thorium.

3C.2 Source material contained in the following products:

3C.2.1 Glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material;

3C.2.2 Glassware containing not more than 10 percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass or ceramic used in construction;

3C.2.3 Glass enamel or glass enamel frit containing not more than 10 percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983; or

3C.2.4 Piezoelectric ceramic containing not more than 2 percent by weight source material.

3C.3 Photographic film, negatives, and prints containing uranium or thorium.

3C.4 Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part.

3C.5 Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:

3C.5.1 The counterweights are manufactured in accordance with a specific license issued by NRC, authorizing distribution by the licensee pursuant to 10 CFR Part 40 (January 1, 2010);

3C.5.2 Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium"; [14]

14 The requirement specified in 3C.5.2 need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights are impressed with the legend, "CAUTION – RADIOACTIVE MATERIAL – URANIUM", as previously required by the regulations.

3C.5.3 Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: “Unauthorized Alterations Prohibited” [15] ; and

15 The requirement specified in 3C.5.3 need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights are impressed with the legend, “CAUTION – RADIOACTIVE MATERIAL – URANIUM", as previously required by the regulations.

3C.5.4 This exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering.

3C.6 Natural or depleted uranium used as shielding constituting part of any shipping container, provided that:

3C.6.1 The shipping container is conspicuously and legibly impressed with the legend "Caution - Radioactive Shielding - Uranium"; and

3C.6.2 The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of 1/8 inch (3.2 mm).

3C.7 Thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium, and that this exemption shall not be deemed to authorize either

3C.7.1 The shaping, grinding, or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens; or

3C.7.2 The receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

3C.8 Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 185 Bq (0.005 µCi) of uranium; or

3C.9 Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that

3C.9.1 The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide); and

3C.9.2 The thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

3C.10 Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following products, any person is exempt from these regulations to the extent that the person receives, possesses, uses, transfers, owns, or acquires the following products [16] :

16 Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

3C.10.1 Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rate:

3C.10.1.1 925 MBq (25 mCi) of tritium per timepiece.

3C.10.1.2 185 MBq (5 mCi) of tritium per hand.

3C.10.1.3 555 MBq (15 mCi) of tritium per dial (bezels when used shall be considered as part of the dial).

3C.10.1.4 3.7 MBq (100 µCi) of promethium-147 per watch or 7.4 MBq (200 µCi) of promethium-147 per any other timepiece.

3C.10.1.5 0.74 MBq (20 µCi) of promethium-147 per watch hand or 1.48 MBq (40 µCi of promethium-147 per other timepiece hand.

3C.10.1.6 2.22 MBq (60 µCi) of promethium-147 per watch dial or 4.44 MBq (120 µCi) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial).

3C.10.1.7 The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(1) For wristwatches, 1 µGy (0.1 mrad) per hour at 10 centimeters from any surface.

(2) For pocket watches, 1 µGy (0.1 mrad) per hour at 1 centimeter from any surface.

(3) For any other timepiece, 2 µGy (0.2 mrad) per hour at 10 centimeters from any surface.

3C.10.1.8 37 kBq (1 µCi) of radium-226 per timepiece in timepieces acquired prior to the effective date of this regulation;

3C.10.2 Precision balances containing not more than 37 MBq (1 mCi) of tritium per balance or not more than 18.5 MBq (0.5 mCi) of tritium per balance part manufactured before December 17, 2007;

3C.10.3 Marine compasses containing not more than 27.8 GBq (750 mCi) of tritium gas and other marine navigational instruments manufactured before December 17, 2007 containing not more than 9.25 GBq (250 mCi) of tritium gas;

3C.10.4 Ionization chamber smoke detectors containing not more than 1 microcurie (µCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

3C.10.5 Electron tubes, provided that:

3C.10.5.1 Each tube does not contain more than one of the following specified quantities of radioactive material:

a.(1) 0.55 GBq (150 mCi) of tritium per microwave receiver protector tube or 370 MBq (10 mCi) of tritium per any other electron tube;

(2) 37 kBq (1 µCi) of cobalt-60;

(3) 185 kBq (5 µCi) of nickel-63;

(4) 1.11 MBq (30 µCi) of krypton-85;

(5) 185 kBq (5 µCi) of cesium-137;

(6) 1.11 MBq (30 µCi) of promethium-147; and further

3C.10.5.2 The radiation dose rate from each electron tube containing radioactive material will not exceed 10 µGy (1 mrad) per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber; [17]

17 For purposes of 3C.10.5, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes,

microwave tubes, indicator tubes, pick up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

3C.10.6 Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:

3C.10.6.1 Each source contains no more than one exempt quantity set forth in Schedule 3B of this part; and

3C.10.6.2 Each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Schedule 3B of this part, provided that the sum of such fractions shall not exceed unity.

3C.10.6.3 For americium-241, 1.85 kBq (0.05 µCi) is considered an exempt quantity under 3C.10.6;

3C.11 Self-luminous products containing radioactive material containing tritium, krypton-85, or promethium-147.

3C.11.1 Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by NRC pursuant to section 32.22 of 10 CFR Part 32 (January 1, 2013), which license authorizes the transfer of the product to persons who are exempt from regulatory requirements.

3C.11.2 The exemption in this section does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.

3C.12 Gas and aerosol detectors containing radioactive material.

3C.12.1 Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, imported, or transferred in accordance with a specific license issued by NRC [18] pursuant to section 32.26 of 10 CFR Part 32 (January 1, 2013); or pursuant to 3.12.3, which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

18 Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

3C.12.2 Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by a state shall be considered exempt under 3C.12.1, provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of 3.12.3.

3C.13 Radioactive drug capsules containing carbon-14 urea for "in vivo" diagnostic use for humans.

3C.13.1 Except as provided in paragraphs 3C.13.2 and 3C.13.3 , any person is exempt from the regulations in this part provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1 µCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

3C.13.2 Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to Part 7.

3C.13.3 Nothing in this section relieves persons from complying with applicable FDA, federal, and state requirements governing receipt, administration, and use of drugs.

PART 3, SCHEDULE 3D: LIMITS FOR BROAD LICENSES (3.11)

Radioactive Material	Col. 1 curies	Col. 2 curies
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	.	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1.
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1.
Cesium-134m	100	1.
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1.
Chromium-51	100	1.
Cobalt-57	10	0.1
Cobalt-58m	100	1.
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1.
Dysprosium-166	10	0.1

Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2 h)	10	0.1
Europium-152 (13 y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1.
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1.
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1.
Indium-113m	100	1.
Indium-114m	1	0.01
Indium-115m	100	1.
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1.
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1.

Osmium-185	1	0.01
Osmium-191m	100	1.
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1.
Platinum-193	10	0.1
Platinum-197m	100	1.
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-186	10	0.1
Rhenium-188	10	0.1
Rhodium-103m	1,000	10.
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1.
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85m	1,000	10.
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulphur-35	10	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1

Technetium-97	10	0.1
Technetium-99m	100	1.
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1.
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-187	10	0.1
Vanadium-48	1	0.01
Xenon-131m	1,000	10.
Xenon-133	100	1.
Xenon-135	100	1.
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01
Zinc-69m	10	0.1
Zinc-69	100	1.
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radioactive material other than source material, special nuclear material, or alpha-emitting radioactive material not listed above.	0.1	0.001

Note 1: To convert Ci to SI units of gigabecquerel (GBq) per liter, multiply the above values by 37.

Example: Zirconium-97 (Col. II) (0.01 Ci multiplied by 37 is equivalent to 0.37 GBq)

PART 3, SCHEDULE 3E: QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE (3.9.11)

Radioactive material [19]	**Release fraction**	**Quantity**	**Quantity**
		TBq	Ci
Actinium-228	.001	148	(4,000)
Americium-241	.001	0.074	(2)

Americium-242	.001	0.074	(2)
Americium-243	.001	0.074	(2)
Antimony-124	.01	148	(4,000)
Antimony-126	.01	222	(6,000)
Barium-133	.01	370	(10,000)
Barium-140	.01	1,100	(30,000)
Bismuth-207	.01	185	(5,000)
Bismuth-210	.01	22.2	(600)
Cadmium-109	.01	37	(1,000)
Cadmium-113	.01	2.96	(80)
Calcium-45	.01	740	(20,000)
Californium-252	.001	0.333	(9)(20 mg)
Carbon-14 (non CO)	.01	1,850	(50,000)
Cerium-141	.01	370	(10,000)
Cerium-144	.01	11.1	(300)
Cesium-134	.01	74	(2,000)
Cesium-137	.01	111	(3,000)
Chlorine-36	.5	3.7	(100)
Chromium-51	.01	11,100	(300,000)
Cobalt-60	.001	185	(5,000)
Copper-64	.01	7,400	(200,000)
Curium-242	.001	2.22	(60)
Curium-243	.001	0.111	(3)
Curium-244	.001	0.148	(4)
Curium-245	.001	0.074	(2)
Europium-152	.01	18.5	(500)
Europium-154	.01	14.8	(400)
Europium-155	.01	111	(3,000)
Germanium-68	.01	74	(2,000)
Gadolinium-153	.01	185	(5,000)
Gold-198	.01	1,110	(30,000)
Hafnium-172	.01	14.8	(400)
Hafnium-181	.01	259	(7,000)
Holmium-166m	.01	3.7	(100)
Hydrogen-3	.5	740	(20,000)
Iodine-125	.5	0.37	(10)
Iodine-131	.5	0.37	(10)
Indium-114m	.01	37	(1,000)
Iridium-192	.001	1,480	(40,000)
Iron-55	.01	1,480	(40,000)
Iron-59	.01	259	(7,000)
Krypton-85	1.0	222,000	(6,000,000)
Lead-210	.01	0.296	(8)
Manganese-56	.01	2,200	(60,000)
Mercury-203	.01	370	(10,000)
Molybdenum-99	.01	1,100	(30,000)
Neptunium-237	.001	0.074	(2)
Nickel-63	.01	740	(20,000)
Niobium-94	.01	11.1	(300)
Phosphorus-32	.5	3.7	(100)
Phosphorus-33	.5	37	(1,000)
Polonium-210	.01	0.37	(10)
Potassium-42	.01	333	(9,000)

Promethium-145	.01	148	(4,000)
Promethium-147	.01	148	(4,000)
Radium-226	0.001	3.7	(100)
Ruthenium-106	.01	7.4	(200)
Samarium-151	.01	148	(4,000)
Scandium-46	.01	111	(3,000)
Selenium-75	.01	370	(10,000)
Silver-110m	.01	37	(1,000)
Sodium-22	.01	333	(9,000)
Sodium-24	.01	370	(10,000)
Strontium-89	.01	111	(3,000)
Strontium-90	.01	3.33	(90)
Sulfur-35	.5	33.3	(900)
Technetium-99	.01	370	(10,000)
Technetium-99m	.01	14,800	(400,000)
Tellurium-127m	.01	185	(5,000)
Tellurium-129m	.01	185	(5,000)
Terbium-160	.01	148	(4,000)
Thulium-170	.01	148	(4,000)
Tin-113	.01	370	(10,000)
Tin-123	.01	111	(3,000)
Tin-126	.01	37	(1,000)
Titanium-44	.01	3.7	(100)
Vanadium-48	.01	259	(7,000)
Xenon-133	1.0	33,300	(900,000)
Yttrium-91	.01	74	(2,000)
Zinc-65	.01	185	(5,000)
Zirconium-93	.01	14.8	(400)
Zirconium-95	.01	185	(5,000)
Any other beta-gamma emitter	.01	370	(10,000)
Mixed fission products	.01	37	(1,000)
Mixed corrosion products	.01	370	(10,000)
Contaminated equipment beta-gamma	.001	370	(10,000)
Irradiated material, any form other than solid noncombustible	.01	37	(1,000)
Irradiated material, solid noncombustible	.001	370	(10,000)
Mixed radioactive waste, beta-gamma	.01	37	(1,000)
Packaged mixed waste, beta-gamma 19	.001	370	(10,000)
Any other alpha emitter	.001	0.074	(2)
Contaminated equipment, alpha	.0001	0.74	(20)
Packaged waste, alpha [20]	.0001	0.74	(20)
Combinations of radioactive materials listed above [19]			

19 For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of

the quantity of each radioactive materials authorized to the quantity listed for that material in Schedule 3E exceeds one.

20 Waste packaged in Type B containers does not require an emergency plan.

PART 3, APPENDIX 3F: CRITERIA RELATING TO USE OF FINANCIAL TESTS AND PARENT COMPANY GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

3F.1 Introduction

3F.1.1 An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This Appendix establishes criteria for passing the financial test and for obtaining the parent company guarantee.

3F.2 Financial Test

3F.2.1 To pass the financial test, the parent company must meet the criteria of either paragraph A.1 or A.2 of this Appendix:

3F.2.1.1 The parent company must have:

(1) Two of the following three ratios: a ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and ratio of current assets to current liabilities greater than 1.5; and

(2) Net working capital and tangible net worth each at least ten times the current decommissioning cost estimates (or prescribed amount if a certification is used); and

(3) Tangible net worth of at least $10 million; and

(4) Assets located in the United States amounting to at least 90 percent of total assets or at least ten times the current decommissioning cost estimates (or prescribed amount if a certification is used).

3F.2.1.2 The parent company must have:

(1) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or AAA, AA, A, or BAA as issued by Moody's; and

(2) Tangible net worth at least ten times the current decommissioning cost estimate (or prescribed amount if a certification is used); and

(3) Tangible net worth of at least $10 million; and

(4) Assets located in the United States amounting to at least 90 percent of total assets or at least ten times the current decommissioning cost estimates (or prescribed amount if certification is used).

3F.2.2 The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform the Department within 90

days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

3F.2.3 Follow-up

3F.2.3.1. After the initial financial test, the parent company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

3F.2.3.2 If the parent company no longer meets the requirements of Paragraph A of this section, the licensee must send notice to the Department of intent to establish alternate financial assurance as specified in the Department's regulations.

(1) The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year-end financial data show that the parent company no longer meets the financial test requirements.

(2) The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

3F.3 Parent Company Guarantee

3F.3.1 The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

3F.3.1,1. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Department. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Department, as evidenced by the return receipts.

3F.3.1.2 If the licensee fails to provide alternate financial assurance as specified in the Department's regulations within 90 days after receipt by the licensee and Department of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

3F.3.1.3 The parent company guarantee and financial test provisions must remain in effect until the Department has terminated the license or until another financial assurance method acceptable to the Department has been put in effect by the licensee.

3F.3.1.4 If a trust is established for decommissioning costs, the trustee and trust must be acceptable to the Department. An acceptable trustee includes the following: an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a state or federal agency.

PART 3, APPENDIX 3G: CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

3G.1 Introduction

3G.1.1 An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning, based on furnishing its own guarantee that funds will be available for

decommissioning costs, and on a demonstration that the company passes the financial test Section II of this Appendix.

3G.1.1.1 The terms of this self-guarantee are in Section III of this Appendix.

3G.1.1.2 This Appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

3G.2 Financial Test

3G.2.1 To pass the financial test, a company must meet the all of the following criteria:

3G.2.1.1 A tangible net worth of at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

3G.2.1.2 Assets located in the United States amounting to at least 90 percent of total assets or at least ten times the current decommissioning cost estimates (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

3G.2.1.3 A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poor's or AAA, AA, or A as issued by Moody's; and

3G.2.2 To pass the financial test, a company must meet all of the following additional requirements:

3G.2.2.1 The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

3G.2.2.2 The company's independent certified public accountant must have compared the data used by the company in the financial test which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement.

(1) In connection with that procedure, the licensee shall inform the Department within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

3G.2.2.3 After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

3G.2.3 If the licensee no longer meets the requirements of 3G.2.1, the licensee must send immediate notice to the Department of its intent to establish alternate financial assurance as specified in the Department's regulations within 120 days of such notice.

3G.3 Company Self-Guarantee

3G.3.1 The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

3G.3.1.1 The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Department.

(1) Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Department, as evidenced by the return receipt.

3G.3.1.2 The licensee shall provide alternative financial assurance as specified in the Department's regulations within 90 days following receipt by the Department of a notice of cancellation of the guarantee.

3G.3.1.3 The guarantee and financial test provisions must remain in effect until the Department has terminated the license or until another financial assurance method acceptable to the Department has been put in effect by the licensee.

3G.3.1.4 The licensee will promptly forward to the Department and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of Section 13 of the Securities and Exchange Act of 1934.

3G.3.1.5 If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors and Moodys, the licensee will provide notice in writing of such fact to the Department within 20 days after publication of the change by the rating service.

(1) If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poors and Moodys, the licensee no longer meets the requirements of 3G.2.1.

3G.3.1.6 The applicant or licensee must provide to the Department a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Department, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

EDITOR'S NOTES

6 CCR 1007-1 has been divided into smaller sections for ease of use. Versions prior to 4/1/07 and rule history are located in the first section, 6 CCR 1007-1. Prior versions can be accessed from the History link that appears above the text in 6 CCR 1007-1. To view versions effective on or after 4/1/07, Select the desired part of the rule, for example 6 CCR 1007-1 Part 1 or 6 CCR 1007-1 Parts 8 - 10.

History

[For history of this section, see Editor's Notes in the first section, 6 CCR 1007-1]