

R313. Environmental Quality, Radiation Control.

R313-22. Specific Licenses.

R313-22-1. Purpose and Authority.

(1) The purpose of this rule is to prescribe the requirements for the issuance of specific licenses.

(2) The rules set forth herein are adopted pursuant to the provisions of Subsections 19-3-104(4) and 19-3-104(8).

R313-22-2. General.

The provisions and requirements of Rule R313-22 are in addition to, and not in substitution for, other requirements of these rules. In particular the provisions of Rule R313-19 apply to applications and licenses subject to Rule R313-22.

R313-22-4. Definitions.

"Alert" means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by off-site response organizations to protect persons off-site.

"Nationally tracked source" is a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix E of 10 CFR 20.1001 to 20.2402 (~~[2007]~~2010), which is incorporated by reference. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

"Principal activities" means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

"Site Area Emergency" means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by off-site response organizations to protect persons off-site.

R313-22-30. Specific License by Rule.

A license by rule is issued in the following circumstances, without the necessity of filing an application for a specific license as required by Subsection R313-22-32(1), and the licensee shall be subject to the applicable provisions of Sections R313-22-33, R313-22-34, R313-22-35, R313-22-36 and R313-22-37:

(1) When a site must be timely remediated of contamination by radioactive materials that are subject to licensing under these

rules but are unlicensed;

(2) When radioactive materials existing as a result of improper handling, spillage, accidental contamination, or unregulated or illegal possession, transfer, or receipt, must be stored and those materials have not been licensed under these rules.

R313-22-32. Filing Application for Specific Licenses.

(1) Applications for specific licenses shall be filed on a form prescribed by the Executive Secretary.

(2) The Executive Secretary may, after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Executive Secretary to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(3) Applications shall be signed by the applicant or licensee or a person duly authorized to act for and on the applicant's behalf.

(4) An application for a license may include a request for a license authorizing one or more activities.

(5) In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Executive Secretary, provided the references are clear and specific.

(6) 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 identify the source or device by manufacturer and model number as registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 (2010), [~~2006 ed. or~~] the equivalent regulations of an Agreement State, or with a State under provisions comparable to 10 CFR 32.210.

(7) As provided by Section R313-22-35, certain applications for specific licenses filed under these rules shall contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning. In the case of renewal applications submitted before January 1, 1995, this submittal may follow the renewal application but shall be submitted on or before January 1, 1995.

(8)(a) Applications to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in Section R313-22-90, "Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release", shall contain either:

(i) An evaluation showing that the maximum dose to a individual off-site due to a release of radioactive materials would not exceed one rem effective dose equivalent or five rems to the thyroid; or

(ii) An emergency plan for responding to a release of radioactive material.

(b) One or more of the following factors may be used to support an evaluation submitted under Subsection R313-22-32(8)(a)(i):

(i) The radioactive material is physically separated so that

only a portion could be involved in an accident;

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

(iii) The release fraction in the respirable size range would be lower than the release fraction shown in Section R313-22-90 due to the chemical or physical form of the material;

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

(v) Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Section R313-22-90;

(vi) Operating restrictions or procedures would prevent a release fraction as large as that shown in Section R313-22-90; or

(vii) Other factors appropriate for the specific facility.

(c) An emergency plan for responding to a release of radioactive material submitted under Subsection R313-22-32(8)(a)(ii) shall include the following information:

(i) Facility description. A brief description of the licensee's facility and area near the site.

(ii) Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.

(iii) Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

(iv) Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

(v) 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 on-site, and a description of the program for maintaining equipment.

(vi) Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

(vii) Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying off-site response organizations and the Executive Secretary; also responsibilities for developing, maintaining, and updating the plan.

(viii) Notification and coordination. A commitment to and a brief description of the means to promptly notify off-site response organizations and request off-site assistance, including medical assistance for the treatment of contaminated injured on-site workers when appropriate. A control point shall be established. The notification and coordination shall be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the Executive Secretary immediately after notification of the appropriate off-site response organizations and not later than one hour after the licensee declares an emergency.

NOTE: These reporting requirements do not supersede or release licensees of complying with the requirements under the

Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499 or other state or federal reporting requirements, including 40 CFR 302, [~~2005-ed~~]2010.

(ix) 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 off-site response organizations and to the Executive Secretary.

(x) Training. 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 special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. 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 the scenarios.

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

(xii) Exercises. Provisions for conducting quarterly communications checks with off-site response organizations and biennial on-site exercises to test response to simulated emergencies. Quarterly communications checks with off-site response organizations shall include the check and update of all necessary telephone numbers. The licensee shall invite off-site response organizations to participate in the biennial exercises. Participation of off-site response organizations in biennial exercises although recommended is not required. Exercises shall use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises shall evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques shall be corrected.

(xiii) 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, Public Law 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

(d) The licensee shall allow the off-site 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 Executive Secretary. The licensee shall provide any comments received within the 60 days to the Executive Secretary with the emergency plan.

(9) An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radioactive drugs for non-commercial transfer to licensees in its consortium authorized for medical use under Rule R313-32 shall include:

(a) A request for authorization for the production of PET radionuclides or evidence of an existing license issued pursuant to 10 CFR Part 30 or equivalent Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(b) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in Subsection R313-22-75(9)(a)(ii).

(c) Identification of the 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 Rule R313-32.

(d) Information identified in Subsection R313-22-75(9)(a)(iii) on the PET drugs to be noncommercially transferred to members of its consortium.

R313-22-33. General Requirements for the Issuance of Specific Licenses.

(1) A license application shall be approved if the Executive Secretary determines that:

(a) the applicant and all personnel who will be handling the radioactive material are qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these rules in a manner as to minimize danger to public health and safety or the environment;

(b) the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or the environment;

(c) the applicant's facilities are permanently located in Utah, otherwise the applicant shall seek reciprocal recognition as required by Section R313-19-30;

(d) the issuance of the license will not be inimical to the health and safety of the public;

(e) the applicant satisfies applicable special requirements in Sections R313-22-50 and R313-22-75, and Rules R313-24, R313-25, R313-32, R313-34, R313-36, or R313-38; and

(f) in the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, or for the conduct of other activities which the Executive Secretary determines will significantly affect the quality of the environment, the Executive Secretary, before commencement of construction of the plant or facility in which the activity will be conducted, has concluded, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. The Executive Secretary shall respond to the application within 60 days. Commencement of construction prior to a response and conclusion shall be grounds for denial of a license to receive and possess radioactive material in the plant or facility. As used in this paragraph the term "commencement of construction" means clearing of land, excavation, or other substantial action that

would adversely affect the environment of a site. The term does not mean site exploration, necessary borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

R313-22-34. Issuance of Specific Licenses.

(1) Upon a determination that an application meets the requirements of the Act and the rules of the Board, the Executive Secretary will issue a specific license authorizing the proposed activity in a form and containing conditions and limitations as the Executive Secretary deems appropriate or necessary.

(2) The Executive Secretary may incorporate in licenses at the time of issuance, additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to Rule R313-22 as he deems appropriate or necessary in order to:

(a) minimize danger to public health and safety or the environment;

(b) require reports and the keeping of records, and to provide for inspections of activities under the license as may be appropriate or necessary; and

(c) prevent loss or theft of material subject to Rule R313-22.

R313-22-35. Financial Assurance and Recordkeeping for Decommissioning.

(1)(a) Applicants for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in Appendix B of 10 CFR 30.1 through 30.72, [~~2006 ed.~~]2010, which is incorporated by reference, shall submit a decommissioning funding plan as described in Subsection R313-22-35(5). The decommissioning funding plan shall also be submitted when a combination of radionuclides is involved if R divided by 10^5 is greater than one, where R is defined here as the sum of the ratios of the quantity of each radionuclide to the applicable value in Appendix B of 10 CFR 30.1 through 30.72, [~~2006 ed.~~]2010, which is incorporated by reference.

(b) Holders of, or applicants for, a specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding 10^{12} times the applicable quantities set forth in Appendix B of 10 CFR 30.1 through 30.72, [~~2006 ed.~~]2010, which is incorporated by reference, or when a combination of isotopes is involved if R , as defined in Subsection R313-22-35(1)(a), divided by 10^{12} is greater than one, shall submit a decommissioning funding plan as described in Subsection R313-22-35(5).

(c) Applicants for a specific license authorizing the possession and use of more than 100 mCi of source material in a readily dispersible form shall submit a decommissioning funding plan as described in Subsection R313-22-35(5).

(2) Applicants for a specific license authorizing possession

and use of radioactive material of half-life greater than 120 days and in quantities specified in Subsection R313-22-35(4), or authorizing the possession and use of source material greater than 10 mCi but less than or equal to 100 mCi in a readily dispersible form shall either:

(a) submit a decommissioning funding plan as described in Subsection R313-22-35(5); or

(b) submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by Subsection R313-22-35(4) using one of the methods described in Subsection R313-22-35(6). Applicants for a specific license authorizing the possession and use of source material in a readily dispersible form shall submit a certification that financial assurance for decommissioning has been provided in the amount of \$225,000 by October 20, 2007. For an applicant subject to this subsection, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but before the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of Subsection R313-22-35(6) shall be submitted to the Executive Secretary before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the Executive Secretary, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements in Subsection R313-22-35(6).

(3)(a) Holders of a specific license issued on or after October 20, 2006, which is of a type described in Subsections R313-22-35(1) or (2), shall provide financial assurance for decommissioning in accordance with the criteria set forth in Section R313-22-35.

(b) Holders of a specific license issued before October 20, 2006, and of a type described in Subsection R313-22-35(1), shall submit by October 20, 2007, a decommissioning funding plan as described in Subsection R313-22-35(5) or a certification of financial assurance for decommissioning in an amount at least equal to \$1,125,000 in accordance with the criteria set forth in Section R313-22-35. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee shall include a decommissioning funding plan in any application for license renewal.

(c) Holders of a specific license issued before October 20, 2006, and of a type described in Subsection R313-22-35(2), shall submit by October 20, 2007, a decommissioning funding plan as described in Subsection R313-22-35(5) or a certification of financial assurance for decommissioning in accordance with the criteria set forth in Section R313-22-35.

(d) A licensee who has submitted an application before October 20, 2006, for renewal of license in accordance with Section R313-22-37, shall provide financial assurance for decommissioning in accordance with Subsections R313-22-35(1) and (2).

(e) Waste collectors and waste processors, as defined in Appendix G of 10 CFR 20.1001 to 20.2402, [~~2006 ed.~~]2010, which is incorporated by reference, shall provide financial assurance in an amount based on a decommissioning funding plan as described in Subsection R313-22-35(5). The decommissioning funding plan shall include the cost of disposal of the maximum amount (curies) of radioactive material permitted by the license, and the cost of disposal of the maximum quantity, by volume, of radioactive material which 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 Rule R313-15.

(f) Holders of a specific license issued prior to October 20, 2006, which is of a type described in Subsections R313-22-35(1), (2), or (3)(g), shall submit a decommissioning funding plan to the Executive Secretary on or before October 20, 2007. Holders of a specific license issued on or after October 20, 2006, which is of a type described in Subsections R313-22-35(1), (2), or (3)(g), shall submit a decommissioning funding plan to the Executive Secretary as a part of the license application.

(g) Applicants for a specific license authorizing the possession and use of radioactive materials in sufficient quantities that require financial assurance and recordkeeping for decommissioning under Section R313-22-35 shall assure that all documents submitted to the Executive Secretary for the purpose of demonstrating compliance with financial assurance and recordkeeping requirements meet the applicable criteria contained in the Nuclear Regulatory Commission's document NUREG-1757, Volume 3, "Consolidated NMSS Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness" (9/2003).

(h) Documents provided to the Executive Secretary under Subsection R313-22-35(3)(g) shall provide that legal remedies be sought in a court of appropriate jurisdiction within Utah.

(4) Table of required amounts of financial assurance for decommissioning by quantity of material. Licensees required to submit an amount of financial assurance listed in this table must do so during a license application or as part of an amendment to an existing license. Licensees having possession limits exceeding the upper bounds of this table must base financial assurance on a decommissioning funding plan.

TABLE

Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of radioactive material, as defined in Appendix B of 10 CFR 30.1 through 30.72 [~~2006 ed.~~] (2010) which is incorporated by reference, in unsealed form. For a combination of radionuclides, if R, as defined in Subsection R313-22-35(1)(a) divided by 10^4 is greater than one but R divided by 10^5 is less than or equal to one:

\$1,125,000

Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of radioactive material, as defined in Appendix B of 10 CFR 30.1 through 30.72 [~~2006 ed.~~] (2010) which is incorporated by reference, in unsealed form. For a combination of radionuclides, if R, as defined in Subsection R313-22-35(1)(a) divided by 10^3 is greater than one but R divided by 10^4 is less than or equal to one: \$225,000

Greater than 10^{10} but less than or equal to 10^{12} times the applicable quantities of radioactive material, as defined in Appendix B of 10 CFR 30.1 through 30.72 [~~2006 ed.~~] (2010) which is incorporated by reference, in sealed sources or plated foils. For combination of radionuclides, if R, as defined in R313-22-35(1)(a), divided by 10^{10} is greater than one, but R divided by 10^{12} is less than or equal to one: \$113,000

(5) A decommissioning funding plan shall contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from Subsection R313-22-35(6), including means for adjusting cost estimates and associated funding levels periodically over the life of the facility. Cost estimates shall be adjusted at intervals not to exceed 3 years. The decommissioning funding plan shall also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of Subsection R313-22-35(6).

(6) Financial assurance for decommissioning shall be provided by one or more of the following methods:

(a) Prepayment. 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 so that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities;

(b) A surety method, insurance, or other guarantee method. These methods shall guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Subsection R313-22-35(8). A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of Section R313-22-35. A guarantee of funds by the applicant or

licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Subsection R313-22-35(9). A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of Section R313-22-35 or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. A surety method or insurance used to provide financial assurance for decommissioning shall contain the following conditions:

(i) the surety method or insurance shall be open-ended or, if written for a specified term, such as five years, shall be renewed automatically unless 90 days or more prior to the renewal date the issuer notifies the Executive Secretary, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance shall also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Executive Secretary within 30 days after receipt of notification of cancellation,

(ii) the surety method or insurance shall be payable to a trust established for decommissioning costs. The trustee and trust shall be acceptable to the Executive Secretary. An acceptable trustee includes 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 Federal or State agency, and

(iii) the surety method or insurance shall remain in effect until the Executive Secretary has terminated the license;

(c) An external sinking fund 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. 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. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions shall be as stated in Subsection R313-22-35(6)(b);

(d) In the case of Federal, State or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in Subsection R313-22-35(4) and indicating that funds for decommissioning will be obtained when necessary; or

(e) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(7) Persons licensed under Rule R313-22 shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in

accordance with Subsection R313-19-34(2), licensees shall transfer all records described in Subsections R313-22-35(7)(a) through (d) to the new licensee. 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. Information the Executive Secretary considers important to decommissioning consists of the following:

(a) records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. 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. These records shall include any known information on identification of involved nuclides, quantities, forms, and concentrations;

(b) as-built drawings and modification of structures and equipment in restricted areas where radioactive materials are used or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations;

(c) except for areas containing only sealed sources, provided the sources have not leaked or no contamination remains after a leak, or radioactive materials having only half-lives of less than 65 days, a list contained in a single document and updated every two years, including all of the following:

(i) all areas designated and formerly designated as restricted areas as defined under Section R313-12-3;

(ii) all areas outside of restricted areas that require documentation under Subsection R313-22-35(7)(a);

(iii) all areas outside of restricted areas where current and previous wastes have been buried as documented under Section R313-15-1109; and

(iv) 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 meet the criteria for decommissioning in Sections R313-15-401 through R313-15-406, or apply for approval for disposal under Section R313-15-1002; and

(d) 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.

(8) Criteria relating to use of financial tests and parent company guarantees for providing reasonable assurance of funds for decommissioning.

(a) To pass the financial test referred to in Subsection R313-22-35(6)(b), the parent company shall meet one of the following criteria:

(i) The parent company shall have all of the following:

(A) 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 a ratio of current assets to current liabilities greater than 1.5;

(B) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates, or prescribed amount if a certification is used;

(C) Tangible net worth of at least \$10 million; and

(D) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates, or prescribed amount if a certification is used; or

(ii) The parent company shall have all of the following:

(A) 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;

(B) Tangible net worth at least six times the current decommissioning cost estimate, or prescribed amount if a certification is used;

(C) Tangible net worth of at least \$10 million; and

(D) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates, or prescribed amount if certification is used.

(b) The parent company's independent certified public accountant shall have compared the data used by the parent 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. In connection with that procedure the licensee shall inform the Executive Secretary 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.

(c)(i) After the initial financial test, the parent company shall repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

(ii) If the parent company no longer meets the requirements of Subsection R313-22-35(8)(a) the licensee shall send notice to the Executive Secretary of intent to establish alternative financial assurance as specified in Section R313-22-35. The notice shall 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. The licensee shall provide alternate financial assurance within 120 days after the end of such fiscal year.

(d) The terms of a parent company guarantee which an applicant or licensee obtains shall provide that:

(i) The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Executive Secretary. 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 Executive Secretary, as evidenced by the return receipts.

(ii) If the licensee fails to provide alternate financial assurance as specified in Section R313-22-35 within 90 days after receipt by the licensee and Executive Secretary 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.

(iii) The parent company guarantee and financial test provisions shall remain in effect until the Executive Secretary has terminated the license.

(iv) If a trust is established for decommissioning costs, the trustee and trust shall be acceptable to the Executive Secretary. An acceptable trustee includes 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 Federal or State agency.

(9) Criteria relating to use of financial tests and self guarantees for providing reasonable assurance of funds for decommissioning.

(a) To pass the financial test referred to in Subsection R313-22-35(6)(b), a company shall meet all of the following criteria:

(i) Tangible net worth 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;

(ii) Assets located in the United States amounting to at least 90 percent of total assets or 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; and

(iii) 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.

(b) To pass the financial test, a company shall meet all of the following additional requirements:

(i) The company shall have at least one class of equity securities registered under the Securities Exchange Act of 1934;

(ii) The company's independent certified public accountant shall have compared the data used by the company in the financial test which is derived from the independently audited, yearend financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Executive Secretary 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; and

(iii) After the initial financial test, the company shall

repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(c) If the licensee no longer meets the requirements of Subsection R313-22-35(9)(a), the licensee shall send immediate notice to the Executive Secretary of its intent to establish alternate financial assurance as specified in Section R313-22-35 within 120 days of such notice.

(d) The terms of a self-guarantee which an applicant or licensee furnishes shall provide that:

(i) The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Executive Secretary. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Executive Secretary, as evidenced by the return receipt.

(ii) The licensee shall provide alternative financial assurance as specified in Section R313-22-35 within 90 days following receipt by the Executive Secretary of a notice of a cancellation of the guarantee.

(iii) The guarantee and financial test provisions shall remain in effect until the Executive Secretary has terminated the license or until another financial assurance method acceptable to the Executive Secretary has been put in effect by the licensee.

(iv) The licensee shall promptly forward to the Executive Secretary 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.

(v) If, at any time, the licensee's most recent bond issuance ceases to be rated in a category of "A" or above by either Standard and Poor's or Moody's, the licensee shall provide notice in writing of such fact to the Executive Secretary within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poor's and Moody's, the licensee no longer meets the requirements of Subsection R313-22-35(9)(a).

(vi) The applicant or licensee shall provide to the Executive Secretary 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 Board, the licensee shall set up and fund a trust in the amount of the current cost estimates for decommissioning.

R313-22-36. Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas.

(1) A specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under Section R313-22-37 no less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days prior to the expiration date stated in the existing license,

the existing license expires at the end of the day on which the Executive Secretary makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(2) A specific license revoked by the Executive Secretary expires at the end of the day on the date of the Executive Secretary's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by an Order issued by the Executive Secretary.

(3) A specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the Executive Secretary notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

(a) limit actions involving radioactive material to those related to decommissioning; and

(b) continue to control entry to restricted areas until they are suitable for release so that there is not an undue hazard to public health and safety or the environment.

(4) Within 60 days of the occurrence of any of the following, a licensee shall provide notification to the Executive Secretary in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release so that there is not an undue hazard to public health and safety or the environment, or submit within 12 months of notification a decommissioning plan, if required by Subsection R313-22-36(7), and begin decommissioning upon approval of that plan if:

(a) the license has expired pursuant to Subsections R313-22-36(1) or (2); or

(b) the licensee has decided to permanently cease principal activities 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 release because of an undue hazard to public health and safety or the environment; or

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

(d) 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 release because of an undue hazard to public health and safety or the environment.

(5) Coincident with the notification required by Subsection R313-22-36(4), the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to Section R313-22-35 in conjunction with a license issuance or renewal or as required by Section R313-22-36. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to Subsection R313-22-36(7)(d)(v).

(a) A licensee who has not provided financial assurance to

cover the detailed cost estimate submitted with the decommissioning plan shall do so on or before August 15, 1997.

(b) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Executive Secretary.

(6) The Executive Secretary may grant a request to extend the time periods established in Subsection R313-22-36(4) if the Executive Secretary determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to Subsection R313-22-36(4). The schedule for decommissioning set forth in Subsection R313-22-36(4) may not commence until the Executive Secretary has made a determination on the request.

(7)(a) A decommissioning plan shall be submitted if required by license condition or 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 Executive Secretary and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(i) procedures would involve techniques not applied routinely during cleanup or maintenance operations;

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

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

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

(b) The Executive Secretary may approve an alternate schedule for submittal of a decommissioning plan required pursuant to Subsection R313-22-36(4) if the Executive Secretary determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(c) Procedures such as those listed in Subsection R313-22-36(7)(a) with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(d) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(i) a description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(ii) a description of planned decommissioning activities;

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

(iv) a description of the planned final radiation survey;

and

(v) an updated 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.

(vi) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in Subsection R313-22-36(8).

(e) The proposed decommissioning plan will be approved by the Executive Secretary if the information therein demonstrates that the decommissioning will be completed as soon as practical and that the health and safety of workers and the public will be adequately protected.

(8)(a) Except as provided in Subsection R313-22-36(9), licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practical but no later than 24 months following the initiation of decommissioning.

(b) Except as provided in Subsection R313-22-36(9), when decommissioning involves the entire site, the licensee shall request license termination as soon as practical but no later than 24 months following the initiation of decommissioning.

(9) The Executive Secretary may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Executive Secretary determines that the alternative is warranted by consideration of the following:

(a) whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(b) whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

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

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

(e) other site-specific factors which the Executive Secretary 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.

(10) As the final step in decommissioning, the licensee shall:

(a) certify the disposition of all licensed material, including accumulated wastes, by submitting a completed Form DRC-14 or equivalent information; and

(b) conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some

other manner that the premises are suitable for release in accordance with the criteria for decommissioning in Sections R313-15-401 through R313-15-406. The licensee shall, as appropriate:

(i) report levels of gamma radiation in units of millisieverts (microrentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters--removable and fixed-- for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(ii) specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(11) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Executive Secretary determines that:

(a) radioactive material has been properly disposed;

(b) reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(c) documentation is provided to the Executive Secretary that:

(i) a radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in Sections R313-15-401 through R313-15-406; or

(ii) other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in Sections R313-15-401 through R313-15-406.

R313-22-37. Renewal of Licenses.

Application for renewal of a specific license shall be filed on a form prescribed by the Executive Secretary and in accordance with Section R313-22-32.

R313-22-38. Amendment of Licenses at Request of Licensee.

Applications for amendment of a license shall be filed in accordance with Section R313-22-32 and shall specify the respects in which the licensee desires the license to be amended and the grounds for the amendment.

R313-22-39. Executive Secretary Action on Applications to Renew or Amend.

In considering an application by a licensee to renew or amend the license, the Executive Secretary will use the criteria set forth in Sections R313-22-33, R313-22-50, and R313-22-75 and in Rules R313-24, R313-25, R313-32, R313-34, R313-36, or R313-38, as applicable.

R313-22-50. Special Requirements for Specific Licenses of Broad Scope.

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 who are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(1) The different types of broad licenses are set forth below:

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

(b) A "Type B 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 Section R313-22-100 for any authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Section R313-22-100, Column I. If two or more radionuclides are possessed thereunder, the possession limits are determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Section R313-22-100, Column I, for that radionuclide. The sum of the ratios for the radionuclides possessed under the license shall not exceed unity.

(c) 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 Section R313-22-100, for any authorized purpose. The possession limit for a Type C broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Section R313-22-100, Column II. If two or more radionuclides are possessed thereunder, the possession limits are determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Section R313-22-100, Column II, for that radionuclide. The sum of the ratios for the radionuclides possessed under the license shall not exceed unity.

(2) An application for a Type A specific license of broad scope shall be approved if all of the following are complied with:

(a) the applicant satisfies the general requirements specified in Section R313-22-33;

(b) the applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

(c) the applicant has established administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(i) 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;

(ii) 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

(iii) 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 committee of safety evaluations of proposed uses prepared in accordance with Subsection R313-22-50(2)(c)(iii)(B) prior to use of the radioactive material.

(3) An application for a Type B specific license of broad scope shall be approved if all of the following are complied with:

(a) the applicant satisfies the general requirements specified in Section R313-22-33;

(b) the applicant has established administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(i) 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

(ii) 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 Subsection R313-22-50(3)(b)(iii)(B) prior to use of the radioactive material.

(4) An application for a Type C specific license of broad scope shall be approved, if:

(a) the applicant satisfies the general requirements specified in Section R313-22-33;

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

(i) a college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

(ii) at least forty 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

(c) the applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, recordkeeping, material control and accounting, and management review necessary to assure safe operations.

(5) Specific licenses of broad scope are subject to the following conditions:

(a) unless specifically authorized by the Executive Secretary, persons licensed pursuant to this section shall not:

(i) conduct tracer studies in the environment involving direct release of radioactive material;

(ii) receive, acquire, own, possess, use, or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;

(iii) conduct activities for which a specific license issued by the Executive Secretary under Section R313-22-75, and Rules R313-25, R313-32 or R313-36 is required; or

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

(b) Type A specific licenses of broad scope issued under Rule R313-22 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.

(c) Type B specific license of broad scope issued under Rule R313-22 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.

(d) Type C specific license of broad scope issued under Rule R313-22 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 Subsection R313-22-50(4).

R313-22-75. Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices Which Contain Radioactive Material.

(1) Licensing the introduction of radioactive material in exempt concentrations into products or materials, and transfer of ownership or possession of the products and materials. [in exempt concentrations-].

(a) The authority to introduce radioactive material in exempt concentrations into equipment, devices, commodities or other products may be obtained only from the Nuclear Regulatory Commission, Washington, D.C. 20555; and

(b) The manufacturer, processor or producer of equipment, devices, commodities or other products containing exempt concentrations of radioactive materials may obtain the authority to transfer possession or control of the equipment, devices,

commodities, or other products containing exempt concentrations to persons who are exempt from regulatory requirements only from the Nuclear Regulatory Commission, Washington, D.C. 20555.

~~[(a) In addition to the requirements set forth in Section R313 22 33, a specific license authorizing the introduction of 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 Subsection R313 19 13(2) (a) will be issued if:~~

~~(i) the applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and~~

~~(ii) the applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Section R313 19 70, that reconcentration of the radioactive material in concentrations exceeding those in Section R313 19 70 is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to a human being.~~

~~(b) Persons licensed under Subsection R313 22 75(1) shall file an annual report with the Executive Secretary which shall identify the type and quantity of products or materials into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product and material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into the product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to Subsection R313 22 75(1) during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within thirty days thereafter.]~~

(2) Licensing the distribution of radioactive material in exempt quantities. Authority to transfer possession or control by the manufacturer, processor or producer of equipment, devices, commodities or other products containing byproduct material whose subsequent possession, use, transfer, and disposal by other persons who are exempted from regulatory requirements may be obtained only from the Nuclear Regulatory Commission, Washington, D.C. 20555.

~~[(a) An application for a specific license to distribute naturally occurring and accelerator produced radioactive material~~

~~(NARM) to persons exempted from these rules pursuant to Subsection R313 19 13(2) (b) will be approved if:~~

~~— (i) the radioactive material is not contained in a food, beverage, cosmetic, drug or other commodity designed for ingestion or inhalation by, or application to, a human being;~~

~~— (ii) the radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into a manufactured or assembled commodity, product, or device intended for commercial distribution; and~~

~~— (iii) the applicant submits copies of prototype labels and brochures and the Executive Secretary approves the labels and brochures;~~

~~— (b) The license issued under Subsection R313 22 75(2) (a) is subject to the following conditions:~~

~~— (i) No more than ten exempt quantities shall be sold or transferred in a single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantities provided the sum of the fractions shall not exceed unity.~~

~~— (ii) Exempt quantities shall be separated and individually packaged. No more than ten packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to Subsection R313 19 13(2) (b). The outer package shall not allow the dose rate at the external surface of the package to exceed 5.0 microsievert (0.5 mrem) per hour.~~

~~— (iii) The immediate container of a quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:~~

~~— (A) identifies the radionuclide and the quantity of radioactivity; and~~

~~— (B) bears the words "Radioactive Material."~~

~~— (iv) In addition to the labeling information required by Subsection R313 22 75(2) (b) (iii), the label affixed to the immediate container, or an accompanying brochure, shall:~~

~~— (A) state that the contents are exempt from Licensing State requirements;~~

~~— (B) bear the words "Radioactive Material — Not for Human Use — Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited — Exempt Quantities Should Not Be Combined;" and~~

~~— (C) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage and disposal of the radioactive material.~~

~~— (e) Persons licensed under Subsection R313 22 75(2) shall maintain records identifying, by name and address, persons to whom radioactive material is transferred for use under Subsection R313 19 13(2) (b) or the equivalent regulations of a Licensing State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity~~

~~of radionuclides transferred under the specific license shall be filed with the Executive Secretary. Reports shall cover the year ending June 30, and shall be filed within thirty days thereafter. If no transfers of radioactive material have been made pursuant to Subsection R313-22-75(2) during the reporting period, the report shall so indicate.~~

~~(3) Licensing the incorporation of naturally occurring and accelerator produced radioactive material (NARM) into gas and aerosol detectors. An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under Subsection R313-19-13(2)(c)(iii) will be approved if the application satisfies requirements equivalent to those contained in 10 CFR 32.26, 2006 ed. The maximum quantity of radium 226 in each device shall not exceed 3.7 kilobecquerel (0.1 mCi).]~~

(3) Reserved

(4) Licensing the manufacture and distribution of devices to persons generally licensed under Subsection R313-21-22(4).

(a) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under Subsection R313-21-22(4) or equivalent regulations of the Nuclear Regulatory Commission, an Agreement State or a Licensing State will be approved if:

(i) the applicant satisfies the general requirements of Section R313-22-33;

(ii) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(A) the device can be safely operated by persons not having training in radiological protection,

(B) under ordinary conditions of handling, storage and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that a person will receive in one year, a dose in excess of ten percent of the annual limits specified in Subsection R313-15-201(1), and

(C) under accident conditions, such as fire and explosion, associated with handling, storage and use of the device, it is unlikely that a person would receive an external radiation dose or dose commitment in excess of the following organ doses:

TABLE

| | |
|---|---------------------|
| Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye | 150.0 mSv (15 rems) |
|---|---------------------|

| | |
|--|--|
| Hands and forearms; feet and ankles; localized areas of skin | |
|--|--|

averaged over areas no
larger than one square
centimeter

2.0 Sv (200 rems)

Other organs

500.0 mSv (50 rems); and

(iii) each device bears a durable, legible, clearly visible label or labels approved by the Executive Secretary, 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 an "on-off" mechanism and indicator, including the maximum time interval for testing, and the identification of radioactive material by radionuclide, 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 No. , Serial No. , are subject to a general license or the equivalent, and the regulations of the Nuclear Regulatory Commission or a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited." The label shall be printed with the words "CAUTION - RADIOACTIVE MATERIAL" and the name of the manufacturer or distributor shall appear on the label. 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 No. , Serial No. , are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited." The label shall be printed with the words "CAUTION - RADIOACTIVE MATERIAL" and the name of the manufacturer or distributor shall appear on the label. 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.

(D) 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 described in Section R313-15-901, and the name of the manufacturer or initial distributor.

(E) Each device meeting the criteria of Subsection R313-21-

22(4)(c)(xiii)(A), bears a permanent label, for example, embossed, etched, stamped, or engraved, affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in Section R313-15-901.

(b) In the event the applicant desires that the device be required to be tested at intervals longer than six 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 a longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Executive Secretary will consider information which includes, but is not limited to:

- (i) primary containment, or source capsule;
- (ii) protection of primary containment;
- (iii) method of sealing containment;
- (iv) containment construction materials;
- (v) form of contained radioactive material;
- (vi) maximum temperature withstood during prototype tests;
- (vii) maximum pressure withstood during prototype tests;
- (viii) maximum quantity of contained radioactive material;
- (ix) radiotoxicity of contained radioactive material; and
- (x) operating experience with identical devices or similarly designed and constructed devices.

(c) In the event the applicant desires that the general licensee under Subsection R313-21-22(4), or under equivalent regulations of the Nuclear Regulatory Commission, an Agreement State or a Licensing State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with this activity or activities, and basis for these estimates. The submitted information shall demonstrate that performance of this 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 dose in excess of ten percent of the annual limits specified in Subsection R313-15-201(1).

(d)(i) If a device containing radioactive material is to be transferred for use under the general license contained in Subsection R313-21-22(4), each person that is licensed under Subsection R313-22-75(4) shall provide the information specified in Subsections R313-22-75(4)(d)(i)(A) through (E) to each person to whom a device is to be transferred. This information must be

provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(A) a copy of the general license contained in Subsection R313-21-22(4); if Subsections R313-21-22(4)(c)(ii) through (iv) or R313-21-22(4)(c)(xiii) do not apply to the particular device, those paragraphs may be omitted;

(B) a copy of Sections R313-12-51, R313-15-1201, and R313-15-1202;

(C) a list of services that can only be performed by a specific licensee;

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

(E) An indication that the Board's policy is to issue civil penalties for improper disposal.

(ii) If radioactive material is to be transferred in a device for use under an equivalent general license of the Nuclear Regulatory Commission, an Agreement State, or Licensing State, each person that is licensed under Subsection R313-22-75(4) shall provide the information specified in Subsections R313-22-75(4)(d)(ii)(A) through (D) to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(A) A copy of an Agreement State's or Licensing State's regulations equivalent to Sections R313-12-51, R313-15-1201, R313-15-1202, and Subsection R313-21-22(4) or a copy of 10 CFR 31.5, 10 CFR 31.2, 10 CFR 30.51, 10 CFR 20.2201, and 10 CFR 20.2202. If a copy of the Nuclear Regulatory Commission regulations is provided to a prospective general licensee in lieu of the Agreement State's or Licensing State's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the Agreement State or Licensing State; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted;

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

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

(D) The name or title, address, and phone number of the contact at the Nuclear Regulatory Commission, Agreement State, or Licensing State from which additional information may be obtained.

(iii) An alternative approach to informing customers may be proposed by the licensee for approval by the Executive Secretary.

(iv) Each device that is transferred after February 19, 2002 must meet the labeling requirements in Subsection R313-22-75(4)(a)(iii).

(v) If a notification of bankruptcy has been made under Section R313-19-34 or the license is to be terminated, each person licensed under Subsection R313-22-75(4) shall provide, upon

request, to the Executive Secretary, the Nuclear Regulatory Commission, or an appropriate Agreement State or Licensing State, records of final disposition required under Subsection R313-22-75(4)(d)(vii)(H).

(vi) Each person licensed under Subsection R313-22-75(4) to initially transfer devices to generally licensed persons shall comply with the requirements of Subsections R313-22-75(4)(d)(vi) and (vii).

(A) The person shall report all transfers of devices to persons for use under the general license under Subsection R313-21-22(4) and all receipts of devices from persons licensed under Subsection R313-21-22(4) to the Executive Secretary. The report must be submitted on a quarterly basis on Form 653, "Transfers of Industrial Devices Report" as prescribed by the Nuclear Regulatory Commission, or in a clear and legible report containing all of the data required by the form.

(B) The required information for transfers to general licensees includes:

(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 alternative 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 device transferred; and

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

(C) 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 persons.

(D) For devices received from a Subsection R313-21-22(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.

(E) If the licensee makes changes to a device possessed by a Subsection R313-21-22(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.

(F) 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.

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

specific licensee.

(H) If no transfers have been made to or from persons generally licensed under Subsection R313-21-22(4) during the reporting period, the report must so indicate.

(vii) The person shall report all transfers of devices to persons for use under a general license in the Nuclear Regulatory Commission's, an Agreement State's, or Licensing State's regulations that are equivalent to Subsection R313-21-22(4) and all receipts of devices from general licensees in the Nuclear Regulatory Commission's, Agreement State's, or Licensing State's jurisdiction to the Nuclear Regulatory Commission, or to the responsible Agreement State or Licensing State agency. The report must be submitted on Form 653, "Transfers of Industrial Devices Report" as prescribed by the Nuclear Regulatory Commission, or in a clear and legible report containing all of the data required by the form.

(A) The required information for transfers to general licensee includes:

(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 alternative 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 persons.

(C) For devices received from a 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 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 must include the license number of the

specific licensee.

(G) If no transfers have been made to or from a Nuclear Regulatory Commission licensee, or to or from a particular Agreement State or Licensing State licensee during the reporting period, this information shall be reported to the Nuclear Regulatory Commission or the responsible Agreement State or Licensing State agency upon request of the agency.

(H) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by Subsection R313-22-75(4)(d)(vii). Records required by Subsection R313-22-75(4)(d)(vii)(H) must be maintained for a period of three years following the date of the recorded event.

(5) Special requirements for the manufacture, assembly or repair of luminous safety devices for use in aircraft. 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 Subsection R313-21-22(5) will be approved if:

(a) the applicant satisfies the general requirements of Section R313-22-33; and

(b) the applicant satisfies the requirements of 10 CFR 32.53 through 32.56 and 32.101 [~~2006 ed.~~] (2010) or their equivalent.

(6) Special requirements for license to manufacture or initially transfer calibration sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under Subsection R313-21-22(7). An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under Subsection R313-21-22(7) will be approved if:

(a) the applicant satisfies the general requirements of Section R313-22-33; and

(b) the applicant satisfies the requirements of 10 CFR 32.57 through 32.59, 32.102 and 10 CFR 70.39 [~~2006 ed.~~] (2010), or their equivalent.

(7) Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license. An application for a specific license to manufacture or distribute radioactive material for use under the general license of Subsection R313-21-22(9) will be approved if:

(a) the applicant satisfies the general requirements specified in Section R313-22-33;

(b) the radioactive material is to be prepared for distribution in prepackaged units of:

(i) iodine-125 in units not exceeding 370 kilobecquerel (ten uCi) each;

(ii) iodine-131 in units not exceeding 370 kilobecquerel (ten uCi) each;

(iii) carbon-14 in units not exceeding 370 kilobecquerel (ten uCi) each;

(iv) hydrogen-3 (tritium) in units not exceeding 1.85 megabecquerel (50 uCi) each;

(v) iron-59 in units not exceeding 740.0 kilobecquerel (20

uCi) each;
(vi) cobalt-57 in units not exceeding 370 kilobecquerel (ten uCi) each;
(vii) selenium-75 in units not exceeding 370 kilobecquerel (ten uCi) each; or
(viii) mock iodine-125 in units not exceeding 1.85 kilobecquerel (0.05 uCi) of iodine-129 and 1.85 kilobecquerel (0.05 uCi) of americium-241 each;

(c) prepackaged units bear a durable, clearly visible label:

(i) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 370 kilobecquerel (ten uCi) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 1.85 megabecquerel (50 uCi) of hydrogen-3 (tritium); 740.0 kilobecquerel (20 uCi) of iron-59; or Mock Iodine-125 in units not exceeding 1.85 kilobecquerel (0.05 uCi) of iodine-129 and 1.85 kilobecquerel (0.05 uCi) of americium-241 each; and

(ii) displaying the radiation caution symbol described in Section R313-15-901 and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals";

(d) one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in 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:

(i) "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 Nuclear Regulatory Commission or of a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority.

.....
Name of Manufacturer"

(ii) "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 a Licensing State.

.....
Name of Manufacturer"

(e) the label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the

source shall also contain directions to the licensee regarding the waste disposal requirements set out in Section R313-15-1001.

(8) Licensing the manufacture and distribution of ice detection devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under Subsection R313-21-22(10) will be approved if:

(a) the applicant satisfies the general requirements of Section R313-22-33; and

(b) the criteria of 10 CFR 32.61, 32.62, 32.103, 2006 ed. are met.

(9) Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under R313-32.

(a) An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to Rule R313-32 will be approved if:

(i) the applicant satisfies the general requirements specified in Section R313-22-33;

(ii) 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 [a drug manufacturer]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 a state agency as a drug manufacturer;

(C) licensed as a pharmacy by a State Board of Pharmacy; or

(D) operating as a nuclear pharmacy within a medical institution[-]; or

(E) registered with a State Agency as a Positron Emission Tomography (PET) drug production facility.

(iii) the applicant submits information on the radionuclide; the 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 to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

(iv) the applicant satisfies the following labeling requirements:

(A) A label is 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. The label must include the radiation symbol 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. For radioactive drugs with a half life greater than 100 days, the time may be omitted.

(B) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for

commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(b) A licensee described by Subsections R313-22-75(9)(a)(ii)(C) or (D):

(i) May prepare radioactive drugs for medical use, as defined in Rule R313-32 (incorporating 10 CFR 35.2 by reference), provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in Subsections R313-22-75(9)(b)(ii) and (iv), or an individual under the supervision of an authorized nuclear pharmacist as specified in Rule R313-32 (incorporating 10 CFR 35.27 by reference).

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

(A) this individual qualifies as an authorized nuclear pharmacist as defined in Rule R313-32 (incorporating 10 CFR 35.2 by reference);

(B) this individual meets the requirements specified in Rule R313-32 (incorporating 10 CFR 35.55(b) and 10 CFR 35.59 by reference) and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(C) this individual is designated as an authorized nuclear pharmacist in accordance with Subsection R313-22-75(9)(b)(iv).

(iii) The actions authorized in Subsections R313-22-75(9)(b)(i) and (ii) are permitted in spite of more restrictive language in license conditions.

(iv) May designate a pharmacist, as defined in Rule R313-32 (incorporating 10 CFR 35.2 by reference), as an authorized nuclear pharmacist if: ~~the individual is identified as of January 1, 1997 as an "authorized user" on a nuclear pharmacy license issued by the Executive Secretary under Subsection R313-22-75(9)]~~

(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.

(v) Shall provide to the Executive Secretary:

(A) a copy of each individual's certification by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or Agreement State as specified in Rule R313-32 (incorporating 10 CFR 35.55(a) by reference) with the written attestation signed by a preceptor as required by Rule R313-32 (incorporating 10 CFR 35.55(b)(2) by reference); or

(B) the Nuclear Regulatory Commission or Agreement State license; or

(C) the permit issued by a licensee of broad scope; or

(D) the permit issued by a U.S. Nuclear Commission master materials licensee; 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

(~~D~~F) [~~and~~] a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to Subsections R313-22-75(9)(b)(ii)(A) and R313-22-75(9)(b)(ii)(C), the individual to work as an authorized nuclear pharmacist.

(c) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. 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. In addition, the licensee shall:

(i) 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

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

(d) Nothing in Subsection R313-22-75(9) relieves the licensee from complying with applicable FDA, or Federal, and State requirements governing radioactive drugs.

(10) Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed under Rule R313-32 for use as a calibration, transmission, or reference source or for the uses listed in Rule R313-32 (incorporating 10 CFR 35.400, 10 CFR 35.500, 10 CFR 35.600, and 35.1000 by reference) will be approved if:

(a) the applicant satisfies the general requirements in Section R313-22-33;

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

(i) the radioactive material contained, its chemical and physical form and amount,

(ii) details of design and construction of the source or device,

(iii) procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

(iv) for devices containing radioactive material, the radiation profile of a prototype device,

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

(vi) procedures and standards for calibrating sources and devices,

(vii) legend and methods for labeling sources and devices as to their radioactive content, and

(viii) instructions for handling and storing the source or device from the radiation safety standpoint, these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided that instructions which are too lengthy for a label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

(c) the label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the source or device is licensed by the Executive Secretary for distribution to persons licensed pursuant to Rule R313-32 (incorporating 10 CFR 35.18, 10 CFR 35.400, 10 CFR 35.500, and 10 CFR 35.600 by reference) or under equivalent regulations of the Nuclear Regulatory Commission, an Agreement State or a Licensing State; provided that labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source;

(d) in the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include in the application sufficient information to demonstrate that a 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

(e) in determining the acceptable interval for test of leakage of radioactive material, the Executive Secretary shall consider information that includes, but is not limited to:

(i) primary containment or source capsule,
(ii) protection of primary containment,
(iii) method of sealing containment,
(iv) containment construction materials,
(v) form of contained radioactive material,
(vi) maximum temperature withstood during prototype tests,
(vii) maximum pressure withstood during prototype tests,
(viii) maximum quantity of contained radioactive material,
(ix) radiotoxicity of contained radioactive material, and
(x) operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(11) Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass-volume applications.

(a) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to Subsection R313-21-21(5) or equivalent regulations of the Nuclear Regulatory Commission or an Agreement State will be approved if:

(i) the applicant satisfies the general requirements specified in Section R313-22-33;

(ii) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses and potential hazards of the industrial product or device to provide reasonable assurance that possession, use or transfer of the depleted uranium in the product or device is not likely to cause an individual to receive a radiation dose in excess of ten percent of the annual limits specified in Subsection R313-15-201(1); and

(iii) the applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(b) In the case of an industrial product or device whose unique benefits are questionable, the Executive Secretary will approve an application for a specific license under Subsection R313-22-75(11) only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(c) The Executive Secretary may deny an application for a specific license under Subsection R313-22-75(11) if the end use of the industrial product or device cannot be reasonably foreseen.

(d) Persons licensed pursuant to Subsection R313-22-75(11)(a) shall:

(i) maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

(ii) label or mark each unit to:

(A) identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

(B) state that the receipt, possession, use and transfer of the product or device are subject to a general license or the equivalent and the regulations of the Nuclear Regulatory Commission or an Agreement State;

(iii) assure that the uranium before being installed in each product or device has been impressed with the following legend clearly legible through a plating or other covering: "Depleted Uranium";

(iv) furnish to each person to whom depleted uranium in a product or device is transferred for use pursuant to the general license contained in Subsection R313-21-21(5) or its equivalent:

(A) a copy of the general license contained in Subsection R313-21-21(5) and a copy of form DRC-12; or

(B) a copy of the general license contained in the Nuclear Regulatory Commission's or Agreement State's regulation equivalent to Subsection R313-21-21(5) and a copy of the Nuclear Regulatory

Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in Subsection R313-21-21(5) and a copy of form DRC-12 with a note explaining that use of the product or device is regulated by the Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in Subsection R313-21-21(5);

(v) report to the Executive Secretary all transfers of industrial products or devices to persons for use under the general license in Subsection R313-21-21(5). The report shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the Executive Secretary and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within thirty days after the end of the calendar quarter in which the product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under Subsection R313-21-21(5) during the reporting period, the report shall so indicate;

(vi) provide certain other reports as follows:

(A) report to the Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the Nuclear Regulatory Commission general license in 10 CFR 40.25 [~~2006 ed.~~] (2010);

(B) report to the responsible state agency all transfers of devices manufactured and distributed pursuant to Subsection R313-22-75(11) for use under a general license in that state's regulations equivalent to Subsection R313-21-21(5),

(C) reports shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within thirty days after the end of each calendar quarter in which a product or device is transferred to the generally licensed person,

(D) if no transfers have been made to Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the Nuclear Regulatory Commission, and

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

(vii) records shall be kept showing the name, address and point of contact for each general licensee to whom the person transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in Subsection R313-21-21(5) or equivalent regulations of the Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in the product or device transferred, and compliance with the report requirements of Subsection R313-22-75(11).

R313-22-90. Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release. Refer to Subsection R313-22-32(8).

TABLE

| Radioactive Material(1) | Release Fraction | Quantity (curies) |
|----------------------------|------------------|-------------------|
| Actinium-228 | 0.001 | 4,000 |
| Americium-241 | .001 | 2 |
| Americium-242 | .001 | 2 |
| Americium-243 | .001 | 2 |
| Antimony-124 | .01 | 4,000 |
| Antimony-126 | .01 | 6,000 |
| Barium-133 | .01 | 10,000 |
| Barium-140 | .01 | 30,000 |
| Bismuth-207 | .01 | 5,000 |
| Bismuth-210 | .01 | 600 |
| Cadmium-109 | .01 | 1,000 |
| Cadmium-113 | .01 | 80 |
| Calcium-45 | .01 | 20,000 |
| Californium-252 (20 mg) | .001 | 9 |
| Carbon-14 | .01 | 50,000 |
| | Non CO | |
| Cerium-141 | .01 | 10,000 |
| Cerium-144 | .01 | 300 |
| Cesium-134 | .01 | 2,000 |
| Cesium-137 | .01 | 3,000 |
| Chlorine-36 | .5 | 100 |
| Chromium-51 | .01 | 300,000 |
| Cobalt-60 | .001 | 5,000 |
| Copper-64 | .01 | 200,000 |
| Curium-242 | .001 | 60 |
| Curium-243 | .001 | 3 |
| Curium-244 | .001 | 4 |
| Curium-245 | .001 | 2 |
| Europium-152 | .01 | 500 |
| Europium-154 | .01 | 400 |
| Europium-155 | .01 | 3,000 |
| Germanium-68 | .01 | 2,000 |
| Gadolinium-153 | .01 | 5,000 |
| Gold-198 | .01 | 30,000 |
| Hafnium-172 | .01 | 400 |
| Hafnium-181 | .01 | 7,000 |
| Holmium-166m | .01 | 100 |
| Hydrogen-3 | .5 | 20,000 |
| Iodine-125 | .5 | 10 |
| Iodine-131 | .5 | 10 |
| Indium-114m | .01 | 1,000 |
| Iridium-192 | .001 | 40,000 |

| | | |
|--|------|-----------|
| Iron-55 | .01 | 40,000 |
| Iron-59 | .01 | 7,000 |
| Krypton-85 | 1.0 | 6,000,000 |
| Lead-210 | .01 | 8 |
| Manganese-56 | .01 | 60,000 |
| Mercury-203 | .01 | 10,000 |
| Molybdenum-99 | .01 | 30,000 |
| Neptunium-237 | .001 | 2 |
| Nickel-63 | .01 | 20,000 |
| Niobium-94 | .01 | 300 |
| Phosphorus-32 | .5 | 100 |
| Phosphorus-33 | .5 | 1,000 |
| Polonium-210 | .01 | 10 |
| Potassium-42 | .01 | 9,000 |
| Promethium-145 | .01 | 4,000 |
| Promethium-147 | .01 | 4,000 |
| Ruthenium-106 | .01 | 200 |
| Radium-226 | .001 | 100 |
| Samarium-151 | .01 | 4,000 |
| Scandium-46 | .01 | 3,000 |
| Selenium-75 | .01 | 10,000 |
| Silver-110m | .01 | 1,000 |
| Sodium-22 | .01 | 9,000 |
| Sodium-24 | .01 | 10,000 |
| Strontium-89 | .01 | 3,000 |
| Strontium-90 | .01 | 90 |
| Sulfur-35 | .5 | 900 |
| Technetium-99 | .01 | 10,000 |
| Technetium-99m | .01 | 400,000 |
| Tellurium-127m | .01 | 5,000 |
| Tellurium-129m | .01 | 5,000 |
| Terbium-160 | .01 | 4,000 |
| Thulium-170 | .01 | 4,000 |
| Tin-113 | .01 | 10,000 |
| Tin-123 | .01 | 3,000 |
| Tin-126 | .01 | 1,000 |
| Titanium-44 | .01 | 100 |
| Vanadium-48 | .01 | 7,000 |
| Xenon-133 | 1.0 | 900,000 |
| Yttrium-91 | .01 | 2,000 |
| Zinc-65 | .01 | 5,000 |
| Zirconium-93 | .01 | 400 |
| Zirconium-95 | .01 | 5,000 |
| Any other beta-gamma emitter | .01 | 10,000 |
| Mixed fission products | .01 | 1,000 |
| Mixed corrosion products | .01 | 10,000 |
| Contaminated equipment, beta-gamma | .001 | 10,000 |
| Irradiated material, any form other than solid noncombustible | .01 | 1,000 |
| Irradiated material, solid noncombustible | .001 | 10,000 |
| Mixed radioactive waste, beta-gamma | .01 | 1,000 |
| Packaged mixed waste, beta-gamma(2) | .001 | 10,000 |

| | | |
|---|-------|-------|
| Any other alpha emitter | .001 | 2 |
| Contaminated equipment, alpha | .0001 | 20 |
| Packaged waste, alpha(2) | .0001 | 20 |
| Combinations of radioactive materials listed above(1) | ----- | ----- |

(1) 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 material authorized to the quantity listed for that material in Section R313-22-90 exceeds one.

(2) Waste packaged in Type B containers does not require an emergency plan.

R313-22-100. Limits for Broad Licenses. Refer to Section R313-22-50.

TABLE

| RADIOACTIVE MATERIAL | COLUMN I | COLUMN II 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 | 1 | 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 (9.2h) | 10 | 0.1 |
| Europium-152 (13y) | 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 | 0.01 |
| 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 |

R313-22-201. Serialization of Nationally Tracked Sources.

Each licensee who manufacturers a nationally tracked source after October 19, 2007, shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

R313-22-210. Registration of Product Information.

Licensees who manufacture or initially distribute a sealed

source or device containing a sealed source whose product is intended for use under a specific license or general license are deemed to have provided reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and the environment if the sealed source or device has been evaluated in accordance with 10 CFR 32.210 [~~2006 ed.~~] (2010) or equivalent regulations of an Agreement State.

KEY: specific licenses, decommissioning, broad scope, radioactive materials

Date of Enactment or Last Substantive Amendment: [~~February 12, 2009~~]

Notice of Continuation: October 5, 2006

Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-3-108