November 24, 1999

TO: Frederick C. Combs, Deputy Director
Office of State Programs

FROM: Clayton Bradt
New York State Department of Labor

SUBJECT: FINAL NEW YORK DEPARTMENT OF LABOR REGULATIONS
"IONIZING RADIATION PROTECTION"

Subsection (c) of Section 38.3 is amended by renumbering paragraphs:

(23) through (66) as (24) through (67);

(67) through (105) as (70) through (108), and

(106) through (117) as (110) through (121).

Subsection (a) of Section 38.3 is amended to add new paragraphs (23), (68), (69), and (109) to read as follows:

(23) "Constraint" (dose constraint) means a value above which, specified licensee actions are required.

(68) "Possess" means to acquire and take responsibility for radiation sources. A licensee or registrant continues to "possess" and be responsible for a radiation source until it is transferred to another licensee or registrant who is authorized to receive the source in accordance with the provisions of this Part, the equivalent regulations of the United States Nuclear Regulatory Commission, or the rules of any other state.

(69) "Principal activities" means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended, excluding storage or disposal of licensed material and excluding activities incidental to decontamination or decommissioning.

(109) "USNRC" means United States Nuclear Regulatory Commission.

Subsection(a) of Section 38.4 is amended to read as follows:

(a) [Every installation and mobile source consisting of radiation equipment or generally licensed devices as required by terms and conditions in Table 3]. Each machine source of ionizing radiation, and each generally licensed device so required by the terms and conditions of Table 3 of Section 38.41 of this Part shall be registered with the [c]Commissioner on a form prescribed by him/her, setting forth the location and character of the radiation source or sources and such other or further information as he or

she may require for the due enforcement of this Part. Registration shall be made prior to receipt of the radiation equipment or upon receipt of the generally licensed device. Regi ration is not complete until it is verified and accepted by the [c]Commissioner. If a registered installation [or mobile source] is so changed as to render its registration inaccurate, notice thereof shall be given to the [c]Commissioner within 48 hours of such change.

A new Subsection (c) is added to Section 38.5 to read as follows:

(c) Specific licenses shall be issued in an accelerated process to authorize possession and use of measuring, gauging or controlling devices (gauges) which are used at fixed locations, and are authorized for distribution to general licensees, but are not included in Table 3 of Section 38.41 of this Part. Such licensees shall comply with Section 38.28, subsection (h) of this Part and the conditions of the specific license, but shall be otherwise exempt from the requirements of Section 38.16 through 38.28 of this Part.

Section 38.9 is amended by taking all verbiage except the title of the Section and inserting said text in a new Subsection (a) as amended to read as follows:

38.9 Duration of licenses and timeliness in decommissioning.

(a) Except as [below] provided in section 38.10 of this Part, a license shall expire at the end of the expiration date therein stated. The filing of an application by the licensee more than 30 days prior to the expiration date for a renewal or a new and superseding license shall extend the license until the [c]Commissioner has finally acted on the application. If a licensee fails to renew his or her license, he or she must immediately cease all use of radioactive materials, transfer all radioactive materials to authorized recipient(s) and comply with the requirements of section 38.23 of

this Part. To terminate a license, the licensee must notify the [c]Commissioner, transfer all radioactive materials to authorized recipients and comply with the provisions of section 38.23 of this Part.

New Subsections (b) through (j) are added to Section 38.9 to read as follows:

(b) Each specific license revoked by the Commissioner expires at the end of the day on the date of the Commissioner's final determination to revoke the license, unless an alternate expiration date is stated in the determination, or is otherwise provided for in the Commissioner's Order.

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

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

(2) continue to control entry to restricted areas until they are suitable for release in accordance with Department requirements.

(d) Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the Department 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 in accordance with Department requirements, or submit within 12 month of notification a decommissioning plan, if required by subsection 38.23(c) of this Part, and begin decommissioning upon approval of that plan if:

(1) the license has expired pursuant to subsection (a) or (b) of this section; or

(2) the licensee has decided to permanently cease principal activities, as defined in this Part, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Department requirements; or

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

(4) 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 in accordance with Department requirements.

(e) Coincident with the notification required by subsection (d) of this section, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to section 38.7 of this Part in conjunction with a license issuance or renewal or as required by this section. 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 section 38.23(c) of this Part.

(1) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this rule becomes effective.

(2) 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 Department.

(f) The Department may grant a request to extend the time periods established in subsection (d) if the Department 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 (d) of this section. The schedule for decommissioning set forth in subsection (d) of this section may not commence until the Department has made a determination on the request.

(1) The Department may approve an alternate schedule for submittal of a decommissioning plan required pursuant to subsection (d) of this section if the Department 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.

(2) 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 of (h) of this section.

(g) (1) Except as provided in subsection (h) of this section, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

(2) Except as provided in subsection (h) of this section, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but not later than 24 months following the initiation of decommissioning.

(h) The Department 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 Department determines that the alternative is warranted by consideration of the following:

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

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

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

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

(5) other site-specific factors which the Department may consider appropriate on a case-by-case basis.

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

(1) certify the disposition of all licensed material, including accumulated wastes;

(2) conduct a radiation survey of the premises where the licensed activities were carried out;

(3) submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in some other manner; and

(4) as appropriate:

(i) report levels of gamma radiation in units of millisieverts (microrem) 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.

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

(1) radioactive material has been properly disposed;

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

(3) (i) a radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with Department requirements; or

(ii) other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with Department requirements.

Subsection (b) of Section 38.17 is amended to read as follows:

(b) develops, documents and implements a radiation protection program commensurate with the scope and extent of the radiation activities engaged in by the radiation installation. This program shall be designed to ensure compliance with the provisions of this Part and the installation operator shall provide a radiation safety officer as described in paragraph [76] 79 of sub[division]section (a) of section 38.3. The radiation officer shall be delegated authority to ensure the implementation of this radiation protection program and shall be responsible for its day-to-day conduct; and

A new Subsection (d) is added to Section 38.17 to read as follows:

(d) implements the ALARA requirements of subsection (a) of this section, and notwithstanding the requirements of subsection 38.19(a) subparagraph (1)(ii) of this Part, constrains air emissions of radioactive materials obtained under the license so that the individual member of the public likely

to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 0.1 mSv (0.01 rem) in a year from these emissions. If a licensee exceeds this dose constraint, the licensee shall report the exceedence as provided in 38.29(c) of this Part, and promptly take appropriate corrective action to ensure against recurrence.

Paragraph (2) of Subsection (h) of Section 38.18 is amended to read as follows:

(2) The licensee or registrant shall review past exposure history and adjust working conditions so as to avoid a monthly [radiation dose] total effective dose equivalent of more than 50 mrem to the embryo/fetus of a declared pregnant woman.

New Subsections (c) and (d) are added to Section 38.20 to read as follows:

(c) Each licensee or registrant shall dispose of unused and unneeded radioactive materials, in a timely manner. Radioactive material which has not been used under a license or registration for a period of 24 months, and radioactive waste which has not been accessed for a period of 24 months shall be considered unused and unneeded and shall be disposed of forthwith.

(d) Each licensee or registrant involved in the transfer for disposal or disposal of radioactive waste shall comply with the provisions of the Title 10 of the Code of Federal Regulations, Part 20, section 20.2006 and Appendix G, January 1, 1997 edition[M].

Subsections (a) and (b) of Section 38.23 are amended to read as follows:

(a) Installations. Each licensee, at least 30 days prior to terminating any license, vacating any installation, or transferring the premises containing such installation, shall permanently decontaminate such installation and premises below or equal to the limits specified in Table 5

of section 38.41 of this Part. A survey shall be made after such decontamination and submitted to the [c]Commissioner. No such installation or premises shall be vacated, sold or transferred until the decontamination survey has been accepted by the [c]Commissioner as demonstrating that the residual radioactive contamination of the installation and premises is as low as is [reasonable] reasonably achievable.

(b) Property. No machinery, instrument, laboratory equipment or any other property used in contact with or in close proximity to radioactive material in a licensed installation shall be assigned, sold, leased or transferred to an unlicensed person unless such property has been permanently decontaminated below or equal to the limits specified in Table 5 of section 38.41 of this Part. A survey shall be made after such decontamination and submitted to the [c]Commissioner. No such property shall be assigned, sold, leased or transferred until such survey has been accepted by the [c]Commissioner as demonstrating that the residual radioactive contamination of the [installation and premises] property is as low as is [reasonable] reasonably achievable.

Subparagraphs (i) and (ii) of Paragraph (4) of Subsection (c) of Section 38.25 are amended to read as follows:

(i) containers holding licensed material in quantities [equal to or] less than the quantities listed in Table 4 of section 38.41; or

(ii) containers holding licensed material in concentrations [equal to or] less than those specified in Appendix B, Table III of section 38.41; or

Subsection (a) of Section 38.27 is amended to read as follows:

(a) Purpose and scope. This section establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in work under a license or registration. [It also describes the

options available to such individuals with regard to inspections by the Department to ascertain compliance of licensees and registrants with the provisions of this Part, commissioner's orders and licenses, regarding radiological working conditions.]

Subsection (d) of Section 38.28 is amended to read as follows:

(d) Records of prior occupational dose. The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in subsection 38.18(e) on the Department form for cumulative occupational radiation exposure history or equivalent until the [commissioner authorizes their disposition] Commissioner terminates each pertinent license or registration, and shall retain the records used in preparing the form or equivalent for three years after the record is made.

Subparagraph (iii) of Paragraph (1) of Subsection (b) of Section 38.29 is amended to read as follows:

(iii) the inability or failure to implement immediate protective actions necessary to avoid exposures to radiation or radioactive materials which could exceed regulatory limits, or releases of radioactive material which could exceed regulatory limits[;due to an event such as a fire, explosion, or toxic gas release].

Clause (e) of Subparagraph (ii) of Paragraph (1) of Subsection (c) of Section 38.29 is amended to read as follows:

(e) any applicable limit in the license or registration; [or]

A new Clause (f) is added to Subparagraph (ii) of Paragraph (1) of Subsection (c) of Section 38.29 as follows:

(f) the ALARA constraint on air emissions established under subsection 38.17(d) of this Part; or

Clause (e) of Subparagraph (i) of Paragraph (2) of Subsection (c) of

Section 38.29 is amended to read as follows:

(e) corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints and associated license or registration conditions.

A new section 38.35 is added to read as follows:

38.35 Special requirements for specific licenses to manufacture or transfer certain items containing naturally occurring or accelerator produced radioactive material.

(a) Licenses for the introduction of radioactive material in exempt concentrations into products or materials, and transfer of ownership or possession:

(1) An application for 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 person, and the subsequent transfer of ownership or possession of the product or material to persons exempt under Table 1, Exemption 2 of Section 38.41 of this Part will be approved if the applicant:

(i) satisfies the general requirements specified in Section 38.8 of this Part;

(ii) provides 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 radioisotopes in the product or material

at the time of transfer; and

(iii) provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Section 38.41, Table 8 of this Part, that reconcentration of the radioactive material in concentrations exceeding those in Table 8 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.

(2) Each person licensed under paragraph (1) of this subsection shall maintain records of transfer of material, and file an annual report with the Department which shall identify:

(i) the type and quantity of each product or material into which radioactive material has been introduced during the reporting period;

(ii) the name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction;

(iii) the type and quantity of radionuclide introduced into each product or material; and

(iv) the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee.

(3) The report required by paragraph (2) of this subsection shall:

(i) indicate whether transfers of radioactive material were made pursuant to paragraph (1) of this subsection, during the reporting period.

(ii) cover the year ending June 30, and be filed by July 31 of the same year.

(b) Licenses for the distribution of naturally occurring and accelerator produced radioactive materials in exempt quantities*.

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

(1) An application for a specific license to distribute radioactive materials to persons exempt under Table 1, Exemption 28 of Section 38.41 of this Part will be approved if:

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

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

(iii) the applicant submits copies of prototype labels and brochures and the Department approves such labels and brochures.

(2) Each license issued under paragraph (1) of this subsection is subject to the following conditions:

(i) No more than 10 exempt quantities shall be sold or transferred in any single transaction. For purposes of this requirement, an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities provided that the sum of such fractions shall not exceed unity.

(ii) Each quantity of radioactive material shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to Section 38.41, Table 1, Exemption 28 of this Part. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

(iii) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which (a) identifies the radioisotope and the quantity of radioactivity, and (b) bears the words "Radioactive Material".

(iv) In addition to the labeling information required by subparagraph (2)(iii) of this subsection, the label affixed to the immediate container, or an accompanying brochure, shall also (a) state that the contents are exempt from State licensing 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.

(3) Each person licensed under paragraph 1 of this subsection shall maintain records of transfer of material identifying, by name and

address, each person to whom radioactive material was transferred for use under Section 38.41, Table 1, Exemption 28 of this Part, or the equivalent regulations of any state, and stating the kinds and quantities of radioactive material transferred. The licensee shall maintain the record of a transfer for a period of one year after the event is included in an annual summary report to the Department.

(4) The annual report required by paragraph (3) of this subsection shall:

(i) indicate whether transfers of radioactive material were made pursuant to paragraph (1) of this subsection, during the reporting period; and

(ii) cover the year ending June 30, and be filed by July 31 of the same year.

(c) Licenses for the incorporation of radioactive material into gas and aerosol detectors.

(1) An application for a specific license to manufacture, process, or produce gas and aerosol detectors containing radioactive material, or to initially transfer such products for use pursuant to Section 38.41, Table 1, Exemption 27 of this Part or equivalent regulations of any state, will be approved if the maximum quantity of radium 226 in each device does not exceed 0.1 microcurie, and if:

(i) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the gas and aerosol detector to demonstrate that the product will meet the safety criteria set forth in paragraph (2) of this subsection. The information should include:

(a) a description of the product and its intended use or uses;

(b) the type and quantity of radioactive material in each unit;

(c) the chemical and physical form of the radioactive material in the product and changes in chemical and physical form that may occur during the useful life of the product;

(d) solubility in water and body fluids of the forms of the radioactive material identified in clauses (c) and (l) of this subparagraph;

(e) details of construction and design of the product as related to containment and shielding of the radioactive material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product;

(f) maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement;

(g) degree of access of human beings to the product during normal handling and use;

(h) total quantity of radioactive material expected to be distributed in the product annually;

(i) the expected useful life of the product;

(j) the proposed methods of labeling or marking the detector and its point--of--sale package to satisfy the requirements of subparagraph (4)(ii) of this subsection;

(k) procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety

features under both normal and severe conditions of handling, storage, use, and disposal of the product;

(l) results of the prototype testing of the product, including any change in the form of the radioactive material contained in the product, the extent to which the radioactive material may be released to the environment, any increase in external radiation levels, and any other changes in safety features;

(m) the estimated external radiation doses and other data relevant to the safety criteria in paragraph (2) of this subsection and the basis for such estimates;

(n) a determination that the probabilities with respect to the doses referred to in subparagraph (2)(iii) of this subsection meet the criteria of that subparagraph;

(o) quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet; and

(p) any additional information, including experimental studies and tests, required by the Department.

(2) Safety criteria.

(a) An applicant for a license under this subsection shall demonstrate that the product is designed and will be manufactured so that:

(i) in normal use and disposal of a single exempt unit, and in normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of

individuals expected to be most highly exposed to radiation or radioactive material from the product, will exceed the dose to the appropriate organ as specified in Column I of the table in paragraph (3) of this subsection;

(ii) it is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life; and

(iii) in use and disposal of a single exempt unit and in handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column II of the table in paragraph (3) of this subsection; and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of that table.*

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* It is the intent of this subparagraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates which are to be made. The following values may be used as guides in estimating compliance with the criteria:

Low -- not more than one such failure per year for each 10,000 exempt units distributed

Negligible -- not more than one such failure per year for each 1 million exempt units distributed.

(3) Table of organ doses.

Part of body	Column I (rem)	Column II (rem)	Column III (rem)
Whole body, head and trunk; active blood-forming organs; gonads; or lens of eye.....	0.005	0.5	15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter.....	0.075	7.5	200
Other organs.....	0.015	1.5	50

(4) Each person licensed under this subsection shall:

(i) Carry out adequate control procedures in the manufacture of the product to assure that each production lot meets the quality control

standards approved by the Department;

(ii) label or mark each detector and its point-of-sale package so that:

(a) each detector has a durable, legible, readily visible label or marking on the external surface of the detector containing:

(1) the following statement: "Contains Radioactive Material";

(2) the name of the radionuclide and quantity of activity; and

(3) an identification of the company licensed to transfer the detector for use pursuant to Section 38.41, Table 1, Exemption 27 of this Part or equivalent regulations of another state.

(b) the labeling or marking specified in clause ii(a) of this paragraph is located where it will be readily visible when the detector is removed from its mounting;

(c) the external surface of the point-of-sale package has a legible, readily visible label or marking containing:

(1) the name of the radionuclide and quantity of activity;

(2) an identification of the person licensed under this subsection to transfer the detector for use pursuant to Section 38.41, Table 1, Exemption 27 of this Part or equivalent regulations of the NRC or another state; and

(3) the following or a substantially similar statement: "This detector contains radioactive material and has been manufactured in compliance with 12 NYCRR Part 38, Subsection 38.35(c). The purchaser is exempt from any regulatory requirements"; and

(d) each detector and point-of-sale package is provided with such other information as may be required by the Department; and

(iii) maintain records and file a report with the Department.

(a) The report must include the following information on products transferred to other persons for use under Section 38.41, Table 1, Exemption 27 of this Part or equivalent regulations of the USNRC or another state:

(1) a description or identification of the type of each product;

(2) for each radionuclide in each type of product, the total quantity of the radionuclide; and

(3) the number of units of each type of product transferred during the reporting period.

(b) The licensee shall file the report within 30 days following:

(1) five years after filing the preceding report; or

(2) notifying the Department of the licensee's decision to permanently discontinue activities authorized pursuant to the license issued under this subsection.

(c) The report must cover the period between the filing of the preceding report and the occurrences specified in subclause (b)(1) or (b)(2) of this subparagraph. If no transfers of radioactive material have been made during the reporting period, the report must so indicate.

(d) The licensee shall maintain the record of a transfer for a period of one year after the event is included in a report to the

Department.

(d) Licensing the Manufacture and Commercial Distribution of Devices to Persons Generally Licensed Under Section 38.41, Table 3, Item (b) of this Part.

(1) An application for a specific license to manufacture or commercially distribute devices containing radioactive material to persons generally licensed under Section 38.41, Table 3, Item (b) or equivalent regulations of the USNRC or an Agreement State, will be approved if:

(i) the applicant satisfies the general requirements of Section 38.8 of this Part;

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

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

(b) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one year a dose in excess of 10 percent of the limits specified in Paragraph (a)(1) of Section 38.18 of this Part;

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

Whole body; head and trunk active blood-forming organs; gonads; or lens of eye	15 rems
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter	200 rems
Other organs	50 rems

(iii) each device bears a durable, legible, clearly visible label or labels approved by the Department, which contain in a clearly identified and separate statement:

(a) instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

(b) the requirement, or lack of requirement, for leak testing, or for testing any "on-off" mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(c) the information called for in one of the following statements, as appropriate, in the same or substantially similar form:

(1) for radioactive material other than NARM:

The receipt, possession, use, and transfer of this device, Model _____*, Serial No. _____*, are subject to a general license or the equivalent and the regulations of the USNRC or a state with which

the 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.

Caution-Radioactive Material

_____

(Name of Manufacturer or Distributor)*

-OR-

(2) for NARM:

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

Caution-Radioactive Material

_____

(Name of Manufacturer or Distributor)*

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*The model, serial number, and name of manufacturer or distributor may be omitted from this label provided they are elsewhere stated in labeling affixed to the device.

(2) 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 such longer interval is justified by performance characteristics of the device or similar devices and by design features that have a significant bearing on the probability or

consequences of radioactive material leakage from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for radioactive material leakage, the Department will consider information that includes, but is not limited to:

(i) primary containment (source capsule);

(ii) protection of primary containment;

(iii) method of sealing containment;

(iv) containment construction materials;

(v) form of contained radioactive material;

(vi) maximum temperature withstood during prototype tests;

(vii) maximum pressure withstood during prototype tests;

(viii) maximum quantity of contained radioactive material;

(ix) radiotoxicity of contained radioactive material; and

(x) operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee under Section 38.41, Table 3, Item (b) of this Part, or under equivalent regulations of the USNRC or another state be authorized to collect the sample to be analyzed by a specific licensee for radioactive material leakage, perform maintenance of the device consisting of replacement of labels, rust and corrosion prevention, and for fixed gauges, maintenance of source holder mounting brackets, test the "on-off" mechanism and indicator, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other

handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10 percent of the limits specified in Paragraph (1) of Subsection 38.18(a) of this Part.

(4) Each person licensed under this paragraph to commercially distribute devices to generally licensed persons shall:

(i) furnish a copy of the general license contained in Section 38.41, Table 3, Item (b) of this Part to each person to whom the licensee directly, or through an intermediate person, commercially distributes radioactive material in a device for use pursuant to the general license;

(ii) furnish a copy of the general license contained in the USNRC's, or a state's regulation equivalent to Section 38.41, Table 3, Item (b) of this Part, or alternatively, furnish a copy of the general license contained in that Section to each person to whom the licensee directly, or through an intermediate person, commercially distributes radioactive material in a device for use pursuant to the general license of the USNRC, this State or another state. If a copy of the general license in Section 38.41, Table 3, Item (b) of this Part is furnished to such a person, it shall be accompanied by an explanation that the use of the device is regulated by the USNRC or a state under requirements substantially the same as those in Section 38.41, Table 3, Item (b) of this Part;

(iii) report to the Department all commercial distributions of such devices to persons for use under the general license in Section 38.41, Table 3, Item (b) of this Part. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Department and the general

licensee, the type, model, serial number of device and serial number of source commercially distributed, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall also include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no commercial distributions have been made to persons generally licensed during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter;

(iv) (a) report to the USNRC all commercial distributions of such devices to persons for use under the NRC general license in 10 CFR 31.5;

(b) report to the appropriate state all transfers of devices manufactured and commercially distributed pursuant to this paragraph for use under a general license in that state's regulations equivalent to Section 38.41, Table 3, Item (b) of this Part;

(c) such reports shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type model, serial number of the device and serial number of source commercially distributed, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall also include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such

a device is commercially distributed to the generally licensed person; and

(d) if no commercial distributions have been made to USNRC or state licensees during the reporting period, the fact that no such distributions have been made shall be reported to the USNRC and the states; and

(v) keep records showing the name, address, and the point of contact for each general licensee to whom the licensee directly, or through an intermediate person, commercially distributes radioactive material in devices for use pursuant to the general license provided in Section 38.41, Table 3, Item (b) of this Part, or equivalent regulations of the USNRC or another state. The records should show the date of each commercial distribution, the isotope and the quantity of radioactivity in each device commercially distributed, the identity of any intermediate person, and compliance with the reporting requirements of this paragraph.

(e) Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer.

(1) An application for a specific license to manufacture, assemble, repair or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under Section 38.41, Table 3, Item (e) of this Part, will be approved if:

(i) the applicant satisfies the general requirements specified in Section 38.8 of this Part;

(ii) the applicant submits sufficient information regarding each device pertinent to evaluation of the potential radiation exposure, including:

(a) chemical and physical form and maximum quantity of

tritium or promethium-147 in each device;

(b) details of construction and design;

(c) details of the method of binding or containing the tritium or promethium-147;

(d) procedures for, and results of, prototype testing to demonstrate that the tritium or promethium-147 will not be released to the environment under the most severe conditions likely to be encountered in normal use;

(e) any quality control procedures proposed as alternatives to those prescribed by paragraph (4) of this subsection; and

(f) any additional information, including experimental studies and tests, required by the Department to facilitate a determination of the safety of the device;

(iii) each device will contain no more than 10 curies of tritium or 300 millicuries of promethium-147. The levels of radiation from each device containing promethium-147 will not exceed 0.5 millirad per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber; and

(iv) the Department determines that:

(a) the method of incorporation and binding of the tritium or promethium-147 in the device is such that the tritium or promethium-147 will not be released under the most severe conditions which are likely to be encountered in normal use and handling of the device;

(b) the tritium or promethium-147 is incorporated or enclosed so as to preclude direct physical contact by any person with it;

(c) the device is so designed that it cannot easily be disassembled; and

(d) the device has been subjected to and has satisfactorily passed the prototype tests prescribed by Schedule B of Part 32 of the Code of Federal Regulations; January 1, 1995 edition [1].

(2) A person licensed under this subsection to manufacture, assemble, or initially transfer devices containing tritium or promethium-147 for distribution to persons generally licensed under Section 38.41, Table 3, Item (e) of this Part shall, except as provided in paragraph (3) below, affix to each device a label containing the radiation symbol prescribed by Section 38.25 of this Part, such other information as may be required by the Department including disposal instructions when appropriate, and the following or a substantially similar statement which contains the information called for in the following statement:

> The receipt, possession, use, and transfer of this device, Model* _____, Serial No.* _____ containing _____ (Identity and quantity of radioactive material) are subject to a general license or the equivalent and the regulations of the U.S.NRC or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority. Do not remove this label.
>
> Caution-Radioactive Material
>
> _____
>
> (Name of manufacturer, assembler, or initial transferor.)*

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*The model, serial number, and name of manufacturer, assembler, or initial transferor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.

(3) If the Department determines that it is not feasible to affix a label to the device containing all the information called for in

paragraph (2) of this subsection, it may waive the requirements of that paragraph and require in lieu thereof that:

(i) a label be affixed to the device identifying:

(a) the manufacturer, assembler, or initial transferor; and

(b) the type of radioactive material; and

(ii) A leaflet bearing the following information be enclosed in or accompany the container in which the device is shipped:

(a) the name of the manufacturer, assembler, or initial transferor;

(b) the type and quantity of radioactive material;

(c) the model number;

(d) a statement that the receipt, possession, use, and transfer of the device are subject to a general license or the equivalent and the regulations of the USNRC or of an Agreement State; and

(e) such other information as may be required by the Department including disposal instructions when appropriate.

(4) Quality assurance

(i) Each person licensed under this subsection shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the tritium or promethium-147.

(ii) Each person licensed under this subsection shall take a random sample of the size required by the table for "Lot Tolerance Percent Defective of 5.0 percent" in Subpart C of Part 32 of the Code of Federal Regulations; January 1, 1995 edition [J], from each inspection lot, and shall subject each unit in the sample to the following tests:

(a) each device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of water entry. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any device which leaks as evidenced by bubbles emanating from within the device, or water entering the device, shall be considered as a defective unit;

(b) the immersion test water from the preceding test in clause (ii)(a) of this paragraph shall be measured for tritium or promethium-147 content by an apparatus that has been calibrated to measure tritium or promethium-147, as appropriate. If more than 0.1 percent of the original amount of tritium or promethium-147 in any device is found to have leaked into the immersion test water, the leaking device shall be considered as a defective unit; and

(c) the levels of radiation from each device containing promethium-147 shall be measured. Any device which has a radiation level in excess of 0.5 millirad per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, shall be considered as a defective unit.

(iii) An application for a license, or for amendment of a license, may include a description of procedures proposed as alternatives to those prescribed by subparagraph (ii) of this paragraph, and proposed criteria for acceptance under those procedures. The Department will approve the proposed alternative procedures if the applicant demonstrates that:

(a) they will consider defective any sampled device which has a leakage rate exceeding 0.1 percent of the original quantity of

tritium or promethium-147 in any 24-hour period; and

(b) the operating characteristic curve or confidence interval estimate for the alternative procedures provides a "Lot Tolerance Percent Defective of 5.0 percent" at the consumer's risk of 0.10.

(iv) No person licensed under this subsection shall transfer to persons generally licensed under Section 38.41, Table 3, Item (e) of this Part:

(a) any luminous safety device which has been tested and found defective under the criteria and procedures specified in this section, unless the defective units have been repaired or reworked and have then met the tests set out in subparagraph (ii) of this paragraph; or

(b) any inspection lot which has been rejected as a result of the procedures in subparagraph (ii) of this paragraph, or alternative procedures in subparagraph (iii) of this paragraph; unless the defective units have been sorted and removed or have been repaired or reworked and have then met the tests set out in subparagraph (ii) of this paragraph.

(5) Material transfer reports.

Each person licensed under this subsection shall file an annual report with the Department which shall state the total quantity of tritium or promethium-147 transferred to persons generally licensed under Section 38.41, Table 3, Item (e) of this Part. The report shall identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report shall cover the year ending June 30 and shall be filed within thirty (30) days thereafter.

(f) Requirements for a license to manufacture or initially transfer

calibration or reference sources containing americium-241, plutonium or radium-226.

(1) An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241, plutonium or radium-226, for distribution to persons generally licensed under Section 38.41, Table 3, Item (f) of this Part, will be approved if:

(i) the applicant satisfies the general requirements of Section 38.8 of this Part;

(ii) the applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

(a) chemical and physical form and maximum quantity of radioactive material in the source;

(b) details of construction and design;

(c) details of the method of incorporation and binding of the radioactive material in the source;

(d) procedures for, and results of, prototype testing of sources, which are designed to contain more than 0.005 microcurie of radioactive material, to demonstrate that the radioactive material contained in each source will not be released or be removed from the source under normal conditions of use;

(e) details of quality control procedures to be followed in manufacture of the source;

(f) a description of labeling to be affixed to the source or the storage container for the source; and

(g) any additional information, including experimental studies and tests, required by the Department to facilitate a determination

of the safety of the source;

(iii) each source will contain no more than 5 microcuries of radioactive material;

(iv) the Department determines, with respect to any type of source containing more than 0.005 microcurie of radioactive material, that:

(a) the method of incorporation and binding of the radioactive material in the source is such that the radioactive material will not be released or be removed from the source under normal conditions of use and handling of the source; and

(b) the source has been subjected to and has satisfactorily passed prototype tests. The following prototype tests shall be conducted, in the order listed, on each of five prototypes of such source:

(1) Initial measurement. The quantity of radioactive material deposited on the source shall be measured by direct counting of the source.

(2) Dry wipe test. The entire radioactive surface of the source shall be wiped with filter paper with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper or by direct measurement of the radioactivity on the source following the dry wipe.

(3) Wet wipe test. The entire radioactive surface of the source shall be wiped with filter paper, moistened with water, with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper after it has dried or by direct measurement of the radioactivity on the source following the wet wipe.

(4) Water soak test. The source shall be immersed

in water at room temperature for a period of 24 consecutive hours. The source shall then be removed from the water. Removal of radioactive material from the source shall be determined by direct measurement of the radioactivity on the source after it has dried or by measuring the radioactivity in the residue obtained by evaporation of the water in which the source was immersed.

(5) Dry wipe test. On completion of the preceding test in this section, the dry wipe test described in sub-clause (2) of this clause shall be repeated.

(6) Observations. Removal of more than 0.005 microcurie of radioactivity in any test prescribed by this clause shall be cause for rejection of the source design. Results of prototype tests submitted to the Department shall be given in terms of radioactivity in microcuries and percent of removal from the total amount of radioactive material deposited on the source.

(2) Labeling of devices.

(i) Each person licensed under this subsection shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement, or a substantially similar statement which contains the information called for in the following statement:

> The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the USNRC or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

Caution-Radioactive Material-this source contains _____.

Do not touch radioactive portion of this source

_____

(Name of manufacturer or initial transferor)

(3) Leak testing of each source.

(i) Each person licensed under this subsection shall perform a dry wipe test upon each source containing more than 0.1 microcurie of radioactive material prior to transferring the source to a general licensee under Section 38.41, Table 3, Item (f) of this Part. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detecting instrumentation capable of detecting 0.005 microcurie of the contained radioactive material. If any such test discloses more than 0.005 microcurie of radioactive material, the source shall be deemed to be leaking or losing radioactive material and shall not be transferred to a general licensee.

(g) Manufacture and Commercial Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under a General License.

An application for a specific license to manufacture or commercially distribute radioactive material for use under the general license of Section 38.41, Table 3, Item (h) of this Part will be approved if:

(1) the applicant satisfies the general requirements specified in Section 38.8 of this Part;

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

(i) iodine-125 in units not exceeding 10 microcuries each;

(ii) iodine-131 in units not exceeding 10 microcuries each;

(iii) carbon-14 in units not exceeding 10 microcuries each;

(iv) hydrogen-3 (tritium) in units not exceeding 50 microcuries each;

(v) iron-59 in units not exceeding 20 microcuries each;

(vi) cobalt-57 in units not exceeding 10 microcuries each;

(vii) selenium-75 in units not exceeding 10 microcuries each; or

(viii) mock iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each;

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

(i) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries of hydrogen-3 (tritium); 20 microcuries of iron-59; or mock iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241; and

(ii) displaying the radiation caution symbol described in Section 38.25(a) of this Part and the words, "Caution, Radioactive Material," and "Not for Internal or External Use in Humans or Animals;" and

(4) one of the following statements, as appropriate, or a substantially similar statement that 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 that accompanies the package:

(i) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories,

or hospitals, and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the USNRC or of a state with which the USNRC has entered into an agreement for the exercise of regulatory authority.

_____

Name of Manufacturer

-OR-

(ii) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories, or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a State.

_____

Name of Manufacturer

-AND-

(5) the label affixed to the unit, or the leaflet or brochure that accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of a mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements of Section 38.20 of this Part.

(h) Ice detection devices containing strontium-90; requirements for

a license to manufacture or initially transfer.

(1) An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 for distribution to persons generally licensed under Section 38.41, Table 3, Item (c) of this Part will be approved if:

(i) the applicant satisfies the general requirements specified in Section 38.8 of this Part;

(ii) the applicant submits sufficient information regarding each type of device pertinent to evaluation of the potential radiation exposure, including:

(a) the chemical and physical form and maximum quantity of strontium-90 in the device;

(b) details of construction and design of the source of radiation and its shielding;

(c) the radiation profile of a prototype device;

(d) procedures for and results of prototype testing of devices to demonstrate that the strontium-90 contained in each device will not be released or be removed from the device under the most severe conditions likely to be encountered in normal handling and use;

(e) details of quality control procedures to be followed in manufacture of the device;

(f) a description of labeling to be affixed to the device;

(g) instructions for handling and installation of the device; and

(h) any additional information, including experimental studies and tests, required by the Department to facilitate a determination

of the safety of the device;

(iii) each device will contain no more than 50 microcuries of strontium-90 in an insoluble form;

(iv) each device will bear durable, legible labeling which includes the radiation caution symbol prescribed by Section 38.25(a) of this Part, a statement that the device contains strontium-90 and the quantity thereof, instructions for disposal and statements that the device may be possessed pursuant to a general license, that the manufacturer or civil authorities should be notified if the device is found, that removal of the labeling is prohibited and that disassembly and repair of the device may be performed only by a person holding a specific license to manufacture or service such devices; and

(v) the Department determines that:

(a) the method of incorporation and binding of the strontium-90 in the device is such that the strontium-90 will not be released from the device under the most severe conditions which are likely to be encountered in normal use and handling of the device;

(b) the strontium-90 is incorporated or enclosed so as to preclude direct physical contact by any individual with it and is shielded so that no individual will receive a radiation exposure to a major portion of his body in excess of 0.5 rem in a year under ordinary circumstance of use;

(c) the device is so designed that it cannot be easily disassembled;

(d) the device has been subjected to and has satisfactorily passed the prototype tests prescribed by Section 32.103 Schedule D of Part 32 of the Code of Federal Regulations; January 1, 1995 edition [R]; and

(e) quality control procedures have been established to satisfy the requirements of paragraph (2) of this subsection.

(2) Quality Assurance:

(i) Each person licensed under this subsection shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the strontium-90.

(ii) Each person licensed under this subsection shall test each device for possible loss of strontium-90 or for contamination by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The detection on the filter paper of more than 2,200 disintegrations per minute of radioactive material per 100 square centimeters of surface wiped shall be cause for rejection of the tested device.

(iii) Each person licensed under this subsection shall take a random sample of the size required by the table for "Lot Tolerance Percent Defective of 5.0 percent" in Subpart C of Part 32 of the Code of Federal Regulations; January 1, 1995 edition [J], from each inspection lot, and shall subject each unit in the sample to the following tests:

(a) Each device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of physical contact between the water and the strontium-90. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any device which leaks, as evidenced by physical contact between the water and the strontium-90, shall be considered as a

defective unit.

(b) The immersion test water from the preceding test in subparagraph (c) (1) of this section shall be measured for radioactive material. If the amount of radioactive material in the immersion test water is greater than 0.1 percent of the original amount of strontium-90 in any device, the device shall be considered as a defective unit.

(iv) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by subparagraph (2)(iii) of this subsection, and proposed criteria for acceptance under those procedures. The Department will approve the proposed alternative procedures if the applicant demonstrates that:

(a) they will consider defective any sampled device which has a leakage rate exceeding 0.1 percent of the original quantity of strontium-90 in any 24-hour period; and

(b) the operating characteristic curve or confidence interval estimate for the alternative procedures provides a "Lot Tolerance Percent Defective of 5.0 percent" at the consumer's risk of 0.10.

(v) No person licensed under this subsection shall transfer to persons generally licensed under Section 38.41, Table 3, Item (c) of this Part:

(a) any device which has been tested and found defective under the criteria and procedures specified in this subsection unless the defective units have been repaired or reworked and then met the tests set out in subparagraph (2)(iii) of this subsection; or

(b) any inspection lot which has been rejected as a result of the procedures in Subpart C of Part 32 of the Code of Federal Regulations; January 1, 1995 edition [J], or alternative procedures in

subparagraph (iv) of this paragraph, unless the defective units have been sorted and removed, or have been repaired or reworked and have then met the tests set out in subparagraph (2)(iii) of this subsection.

(i) Manufacture and distribution of sources or devices containing radioactive material for medical use.

(1) An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Part 35 of the Code of Federal Regulations or the equivalent regulations of any state, for use as a calibration or reference source or for medical diagnosis or therapy, will be approved if:

(i) the applicant satisfies the general requirements in Section 38.8 of this Part;

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

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

(b) details of design and construction of the source or device;

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

(d) the radiation profile of a prototype device;

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

(f) procedures and standards for calibrating sources and

devices;

(g) legend and methods for labeling sources and devices as to their radioactive content; and

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

(iii) 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 Department has approved distribution of the (name of source or device) to persons licensed to use radioactive material identified in Section 35.58, 35.400 or 35.500, as appropriate, of Part 35 of the Code of Federal Regulations or the equivalent regulations of a state.

(2) (i) 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, he or she shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

(ii) In determining the acceptable interval for test of leakage of radioactive material, the Department will consider information

that includes, but is not limited to:

(a) primary containment (source capsule);

(b) protection of primary containment;

(c) the method of sealing containment;

(d) containment construction materials;

(e) the form of contained radioactive material;

(f) the maximum temperature withstood during prototype tests;

(g) the maximum pressure withstood during prototype tests;

(h) the maximum quantity of contained radioactive material;

(i) the radiotoxicity of contained radioactive material; and

(j) operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(j) Manufacture, preparation or transfer for commercial distribution of drugs containing radioactive material for medical use under Part 35 of the Code of Federal Regulations or the equivalent regulations of any state.

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to Part 35 of the Code of Federal Regulations or the equivalent regulations of any state will be approved if:

(i) the applicant satisfies the general requirements specified in Section 38.8 of this Part;

(ii) the applicant submits evidence that the applicant is

registered or licensed by the New York State Board of Pharmacy as a drug manufacturer or a pharmacy, as appropriate to their practice;

(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; and

(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.

(2) 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;

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

(iii) use differing activity concentrations in preparing different radiopharmaceuticals, and ensure that any discrepancy between the calculated volume of a dosage and the volume found to be required by measurement to achieve the prescribed activity, is resolved before the dosage is dispensed. Records of actions taken to resolve any such discrepancy shall be maintained for three years.

(3) A licensee shall possess and use instrumentation for performing surveys and analyses for radioactive contamination, and for making such measurements of radiation levels and radiation dose as may be necessary to demonstrate compliance with all requirements of this Part. In addition, the licensee shall:

(i) provide appropriate instrumentation for each application. This must include but is not limited to: a microrem meter for surveying non-radioactive trash before disposal, and for surveying workers' skin and clothing for contamination; a thyroid uptake system with a reproducible geometry and an adequate lower limit of detection; and analytical instruments for identifying and quantifying radioactive contamination; and

(ii) calibrate all instruments in accordance with the manufacturer's specifications, and calibrate all meters at least every 12 months.

(4) (i) A licensee shall provide a Radiation Safety Officer who is a Health Physicist with qualifications listed below in subparagraph (iii) of this paragraph.

(ii) A licensee shall only allow persons who are certified by the New York State Board of Pharmacy as nuclear pharmacists to act as pharmacists in a facility licensed pursuant to this subsection. A licensee may also propose such a certified nuclear pharmacist as Radiation Safety Officer provided that the nuclear pharmacist will be assisted in the administration of the radiation protection program by a Health Physicist with the qualifications listed below in subparagraph (iii) of this paragraph, and who will be present at the licensee's facility for the equivalent of one working day per month at a minimum, and who will provide the following services:

(a) provide classroom instruction to non-professional personnel who will perform work under the license;

(b) review personnel monitoring reports and recommend methods to reduce exposures exceeding ALARA levels;

(c) review survey records and make confirmatory measurements;

(d) review air monitoring and emission levels and ensure compliance with limits;

(e) assist in thyroid bioassays and review absorbed dose calculations;

(f) observe operations and make recommendations for

improvements;

(g) assist in response to, and in the evaluation of root causes and impacts of, incidents and accidents in order to minimize their impact and prevent their recurrence; and

(h) generally consult with the RSO and provide health physics support as needed. The services to be provided must be documented in a contractual agreement between the licensee and the health physicist, and the Department must be given a minimum of thirty days advance notice of the licensee's intent to retain a different health physicist.

(iii) A health physicist who will act as Radiation Safety Officer, or who will provide the services described in subparagraph (ii) of this paragraph above, must have the following qualifications:

(a) experience in performing radiation protection services, or the duties of a Radiation Safety Officer for programs of similar type, size and scope as the licensee's program; and

(b) a Bachelor's degree in health physics or radiological health and four years of the experience as described in clause (a) of this subparagraph above; or Certification by the American Board of Health Physics (Comprehensive), the American Board of Radiology in Medical Nuclear Physics, the American Board of Science in Nuclear Medicine in Radiation Protection or the American Board of Medical Physics in Medical Health Physics, and two years of the experience as described in clause (a) of this subparagraph above.

(5) (i) A licensee shall only locate a nuclear pharmacy in a building that is zoned for commercial use, and which is not in a heavy public traffic area such as a large shopping center.

(ii) A licensee who proposes to locate within a multi-tenant

building must demonstrate that:

(a) there are no areas above or below the proposed facility which are not under the licensee's control, and to which the licensee does not have the authority to restrict access; and

(b) there are no neighboring tenants on the same level with walls contiguous to the proposed radioactive materials use and storage areas. There must be a buffer zone of unrestricted area within the licensee's proposed facility along any walls that are common walls with a neighboring tenant.

A new Section 38.36 is added to read as follows:

38.36 Specific requirements for irradiators.

(a) Purpose. The requirements of this section apply to panoramic irradiators that have either dry or wet storage of radioactive sealed sources, and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sources in air or water, as applicable for the type of irradiator, are covered by this section. The requirements of this section are in addition to other requirements of this Part, and nothing in this section relieves the licensee from complying with other applicable regulations for siting, zoning, land use and building code requirements for industrial facilities.

(b) Specific requirements. Each person who constructs or operates an irradiator shall comply with the provisions of Title 10 of the Code of Federal Regulations, "Licenses and Radiation Safety Requirements for Irradiators," Part 36, January 1, 1995 edition [L].

Section 38.41 is amended to read as follows:

38.41 Tables and appendices. The tables and appendices hereto annexed and designated "Table 1-Exemptions," "Table 2-Exempt Quantities," Table 3-General Licenses: Items, Terms and Conditions", "Table 4-Quantities of Licensed Material," "Table 5-Acceptable Surface Contamination Levels," "Table 6-Protection Factors for Respirators," "Table 7-Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," "Table 8-Exempt Concentrations," "Appendix A-A_1 and A_2 Values for Radionuclides," "Appendix B-Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sanitary Sewerage," and "Appendix C-Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning" are hereby made provisions of this Part.

Exemption 2 in Table 1 of Section 38.41 is amended to read as follows:

Exemption 2. Radioactive material contained in any item in a concentration not exceeding that set forth in Table [2] 8. No person may introduce radioactive material into a product or material when such person knows or has reason to believe that such product or material will be transferred to persons who are exempt under this Exemption or equivalent regulations of the United States Nuclear Regulatory Commission or any [a]Agreement [s]State, unless such introduction or transfer is accomplished in accordance with a specific license or permit issued pursuant to this Part or by the State Department of Health, the New York City Department of Health, the United States Nuclear Regulatory Commission or any [a]Agreement [s]State, and such specific license or permit expressly authorizes such introduction. For the purposes of this Exemption, the processing of materials or items which results in an increase in the concentration of radioactive material

therein shall be deemed to be the same as introduction by the addition of radioactive material.

Exemption 28 in Table 1 of Section 38.41 is amended to read as follows:

Exemption 28. Radioactive material contained in individual, packaged quantities each of which does not exceed the value listed in Table [4] 2 of this Part. For purposes of this Exemption, an individual, packaged quantity may be composed of fractional parts of one or more of the exempt quantities, provided that the sum of such fractions[, as given in the Note to Table 4 of this Part,] shall not exceed unity. There shall be no commercial distribution or human use of radioactive material possessed under this Exemption. Also, sources obtained under this exemption shall not be used in a combination that exceeds the value listed in Table 2 of this Part for a single radionuclide, or the sum of the fractions for more than one radionuclide, as a source of ionizing radiation in any device designed for use in detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or designed for producing light or an ionized atmosphere. Radioactive material exempted under this Part effective October 15, 1962, and which are larger in quantity than listed in Table [4] 2 and obtained before September 1, 1971 shall continue to be exempt.

Exemption 29 in Table 1 of Section 38.41 is amended to read as follows:

Exemption 29. Radioactive [material] sources contained in or on ionizing radiation measuring instruments for purposes of internal calibration or standardization. [not exceeding] No source shall exceed the [exempt] quantity set forth in Table [4] 2 of this Part, or [less than] 0.05 microcurie of Americium-241 [in each source], and each instrument shall contain no more than 10 such sources. For purposes of this Exemption, each

source may contain more than one radionuclide [in which case the limitations of Note 2, Table 4 the note to Table 2 of this Part on the activity of each radionuclide in each source shall be adhered to]. An individual exempt quantity may be composed of fractional parts of the exempt quantities in Table 2 of this Part, provided that the sum of the fractions shall not exceed unity. Such sources shall be produced, manufactured, processed, imported or transferred in accordance with a specific license issued by the United States Nuclear Regulatory Commission, an [a]Agreement State or a licensing non-[a]Agreement State. Such license shall authorize the transfer of such calibration sources to persons exempt [form] from the requirements of this Part or equivalent regulations of the United States Nuclear Regulatory Commission or an [a]Agreement State.

Table 2 is added to Section 38.41 to read as follows:

TABLE 2
EXEMPT QUANTITIES

Radionuclide	Exempt quantity (microcuries)
Antimony 122 (Sb 122)	100
Antimony 124 (Sb 124)	10
Antimony 125 (Sb 125)	10
Arsenic 73 (As 73)	100
Arsenic 74 (As 74)	10
Arsenic 76 (As 76)	10
Arsenic 77 (As 77)	100
Barium 131 (Ba 131)	10
Barium 133 (Ba 133)	10
Barium 140 (Ba 140)	10
Beryllium (Be 7)	100
Bismuth 210 (Bi 210)	1
Bromine 82 (Br 82)	10
Cadmium 109 (Cd 109)	10
Cadmium 115m (Cd 115m)	10
Cadmium 115 (Cd 115)	100
Calcium (Ca 45)	10
Calcium 47 (Ca 47)	10
Carbon 14 (C 14)	100
Cerium 141 (Ce 141)	100
Cerium 143 (Ce 143)	100
Cerium 144 (Ce 144)	1
Cesium 131 (Cs 131)	1,000
Cesium 134m (Cs 134m)	100
Cesium 134 (Cs 134)	1
Cesium 135 (Cs 135)	10
Cesium 136 (Cs 136)	10
Cesium 137 (Cs 137)	10
Chlorine 36 (Cl 36)	10
Chlorine 38 (Cl 38)	10
Chromium 51 (Cr 51)	1,000
Cobalt 58m (Co 58m)	10
Cobalt 58 (Co 58)	10
Cobalt 60 (Co 60)	1
Copper 64 (Cu 64)	100
Dysprosium 165 (Dy 165)	10
Dysprosium 166 (Dy 166)	100
Erbium 169 (Er 169)	100
Erbium 171 (Er 171)	100
Europium 152 (Eu 152) 9.2h	100

Europium 152 (Eu 152) 13 yr	1
Europium 154 (Eu 154)	1
Europium 155 (Eu 155)	10
Fluorine 18 (F 18)	1,000
Gadolinium 153	10
Gadolinium 159 (Gd 159)	1100
Gallium 72 (Ga 72)	10
Germanium 71 (Ge 71)	100
Gold 198 (Au 198)	100
Gold 199 (Au 199)	100
Hafnium 181 (Hf 181)	10
Holmium 166 (Ho 166)	100
Hydrogen 3 (H 3)	1,000
Indium 113m (In 113m)	100
Indium 114m (In 114m)	10
Indium 114 (In 114)	1
Indium 115m (In 115m)	100
Indium 115 (In 115)	10
Iodine 125 (I 125)	1
Iodine 126 (I 126)	1
Iodine 129 (I 129)	0.1
Iodine 131 (I 131)	1
Iodine 132 (I 132)	10
Iodine 133 (I 133)	1
Iodine 134 (I 134)	10
Iodine 135 (I 135)	10
Iridium 192 (Ir 192)	10
Iridium 194 (Ir 194)	100
Iron 55 (Fe 55)	100
Iron 59 (Fe 59)	10
Krypton 85 (Kr 85)	100
Krypton 87 (Kr 87)	10
Lanthanum 140 (La 140)	10
Lutetium 177 (Lu 177)	100
Manganese 52 (Mn 52)	10
Manganese 54 (Mn 54)	10
Manganese 56 (Mn 56)	10
Mercury 197m (Hg 197m)	100
Mercury 197 (Hg 197)	100
Mercury 203 (Hg 203)	10
Molybdenum 99 (Mo 99)	100
Neodymium 147 (Nd 147)	100
Neodymium 149 (Nd 149)	100
Nickel 59 (Ni 59)	100
Nickel 63 (Ni 63)	10
Nickel 65 (Ni 65)	100
Niobium 93m (Nb 93m)	10

Niobium 95 (Nb 95)	10
Niobium 97 (Nb 97)	10
Osmium 185 (Os 185)	10
Osmium 191m (Os 191m)	100
Osmium 191 (Os 191)	100
Osmium 193 (Os 193)	100
Palladium 103 (Pd 103)	100
Palladium 109 (Pd 109)	100
Phosphorus 32 (P 32)	10
Platinum 191 (Pt 191)	100
Platinum 193m (Pt 193m)	100
Platinum 193 (Pt 193)	100
Platinum 197m (Pt 197m)	100
Platinum 197 (Pt 197)	100
Polonium 210 (Po 210)	0.1
Potassium 42 (K 42)	10
Praseodymium 142 (Pr 142)	100
Praseodymium 143 (Pr 143)	100
Promethium 147 (Pm 147)	10
Promethium 149 (Pm 149)	10
Radium 226 (Ra 226)	0.1
Rhenium 186 (Re 186)	100
Rhenium 188 (Re 188)	100
Rhodium 103m (Rh 103m)	100
Rhodium 105 (Rh 105)	100
Rubidium 86 (Rb 86)	10
Rubidium 87 (Rb 87)	10
Ruthenium 97 (Ru 97)	100
Ruthenium 103 (Ru 103)	10
Ruthenium 105 (Ru 105)	10
Ruthenium 106 (Ru 106)	1
Samarium 151 (Sm 151)	10
Samarium 153 (Sm 153)	100
Scandium 46 (Sc 46)	10
Scandium 47 (Sc 47)	100
Scandium 48 (Sc 48)	10
Selenium 75 (Se 75)	10
Silicon 31 (Si 31)	100
Silver 105 (Ag 105)	10
Silver 110m (Ag 110m)	1
Silver 111 (Ag 111)	100
Sodium 22 (Na 22)	10
Sodium 24 (Na 24)	10
Strontium 85 (Sr 85)	10
Strontium 89 (Sr 89)	1
Strontium 90 (Sr 90)	0.1
Strontium 91 (Sr 91)	10

Strontium 92 (Sr 92)	10
Sulphur 35 (S 35)	100
Tantalum 182 (Ta 182)	10
Technetium 96 (Tc 96)	10
Technetium 97m (Tc 97m)	100
Technetium 97 (Tc 97)	100
Technetium 99m (Tc 99m)	100
Technetium 99 (Tc 99)	10
Tellurium 125m (Te 125m)	10
Tellurium 127m (TE 127m)	10
Tellurium 127 (Te 127)	100
Tellurium 129m (Te 129m)	10
Tellurium 129 (Te 129)	100
Tellurium 131m (Te 131m)	10
Tellurium 132 (Te 132)	10
Terbium 160 (Tb 160)	10
Thallium 200 (Tl 200)	100
Thallium 201 (TI 201)	100
Thallium 202 (Ti 202)	100
Thallium 204 (Tl 204)	10
Thulium 170 (Tm 170)	10
Thulium 171 (Tm 171)	10
Tin 113 (Sn 113)	10
Tin 125 (Sn 125)	10
Tungsten 181 (W 181)	10
Tungsten 185 (W 185)	10
Tungsten 187 (W 187)	100
Vanadium 48 (V 48)	10
Xenon 131m (Xe 131m)	1,000
Xenon 133 (Xe 133)	100
Xenon 135 (Xe 135)	100
Ytterbium 175 (Yb 175)	100
Yttrium 90 (Y 90)	10
Yttrium 91 (Y 91)	10
Yttrium 92 (Y 92)	100
Yttrium 93 (Y 93)	100
Zinc 65 (Zn 65)	10
Zinc 69 (Zn 69)	1,000
Zinc 69m (Zn 69m)	100
Zirconium 93 (Zr 93)	10
Zirconium 95 (Zr 95)	10
Zirconium 97 (Zr 97)	10
Radioactive material other than alpha emitting radioactive material not listed above	0.1

Phrase (i) of Subitem (2) of Item (a) in Table 3 of Section 38.41 is amended to read as follows:

(i) Such person shall not [be] by any method combine, increase or cause any combination or increase in the radioactivity of any device containing radioactive material, or administer externally or internally, or direct the administration of, any device to a human being for any purpose.

A new Phrase (i) is added to Subitem (1) of Item (b) in Table 3 of Section 38.41 to read as follows:

(i) Such devices contain no more than one millicurie of gamma-emitting radioactive material, where gamma radiation is the emission of interest; and contain no more than one millicurie of strontium 90 or of any transuranic radionuclide.

Old Phrases (i) through (iii) of Subitem (1) of Item (b) in Table 3 of Section 38.41 are redesignated Phrases (ii) through (iv).

Subitem (1) of Item (h) in Table 3 of Section 38.41 is changed to read:

(1) A general license is hereby issued to own, receive, acquire, possess, transfer and use radioactive material as specified below for certain in vitro clinical or laboratory tests by a physician[s], veterinarian, clinical laboratory or hospital. Such radioactive material shall be manufactured in accordance with a [specified] specific license issued by the commissioner, the State Department of Health, the New York City Department of Health, the United States Nuclear Regulatory Commission or any [a]Agreement State or any licensing non-[a]Agreement State and such license shall authorize distribution under the general license of this Item or its equivalent provided that:

Phrase (ii) of Subitem (1) of Item (h)in Table 3 of Section 38.41 is changed to read as follows (subphrases (a) through (h) of the phrase (ii)

remain unchanged):

(ii) Such radioactive material is limited for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or radiation therefrom, to human beings or animals and is limited to the following radionuclides:

Table 8 is added to Section 38.41 to read as follows:

TABLE 8
EXEMPT CONCENTRATIONS

Element (atomic number)	Radionuclide	Column I Gas concentration (μCi/ml (1))	Column II Liquid and solid concentration (μCi/ml (2))
Antimony (51)	Sb 122		3x10- (4)
	Sb 124		2x10- (4)
	Sb 125		1x10- (3)
Argon (18)	A 37	1x10- (3)	
	A 41	4x10- (7)	
Arsenic (33)	As 73		5x10- (3)
	As 74		5x10- (4)
	As 76		2x10- (4)
	As 77		8x10- (4)
Barium (56)	Ba 131		2x10- (3)
	Ba 140		3x10- (4)
Beryllium (4)	Be 7		2x10- (2)
Bismuth (83)	Bi 206		4x10- (4)
Bromine (35)	Br 82	4x10- (7)	3x10- (3)
Cadmium (48)	Cd 109		2x10- (3)
	Cd 115m		3x10- (4)
	Cd 115		3x10- (4)
Calcium (20)	Ca 45		9x10- (5)
	Ca 47		5x10- (4)
Carbon (6)	C 14	1x10- (6)	8x10- (5)
Cerium (58)	Ce 141		9x10- (4)
	Ce 143		4x10- (4)
	Ce 144		1x10- (4)
Cesium (55)	Cs 131		2x10- (2)
	Cs 134m		6x10- (2)
	Cs 134		9x10- (5)
Chlorine (17)	Cl 38	9x10- (7)	4x10- (3)
Chromium (24)	Cr 51		2x10- (2)
Cobalt (27)	Co 57		5x10- (3)
	Co 58		1x10- (3)
	Co 60		5x10- (4)
Copper (29)	Cu 64		3x10- (3)
Dysprosium (66)	Dy 165		4x10- (2)
	Dy 166		4x10- (4)
Erbium (68)	Er 169		9x10- (4)
	Er 171		1x10- (3)
Europium (63)	Eu 152 (T/2=9.2 Hrs.)		6x10- (4)

	Eu 155		2x10- (2)
Fluorine (9)	F 18	2x10- (6)	8x10- (3)
Gadolinium (64)	Gd 153		2x10- (3)
	Gd 159		8x10- (4)
Gallium (31)	Ga 72		4x10- (4)
Germanium (32)	Ge 71		2x10- (2)
Gold (79)	Au 196		2x10- (3)
	Au 198		5x10- (4)
	Au 199		2x10- (3)
Hafnium (72)	Hf 181		7x10- (4)
Hydrogen (1)	H 3	5x10- (6)	3x10- (2)
Indium (49)	In 113m		1x10- (2)
	In 114m		2x10- (4)
Iodine (53)	I 126	3x10- (9)	2x10- (5)
	I 131	3x10- (9)	2x10- (5)
	I 132	8x10- (8)	6x10- (4)
	I 133	1x10- (6)	7x10- (5)
	I 134	2x10- (7)	1x10- (3)
..dium (77)	Ir 190		2x10- (3)
	Ir 192		4x10- (4)
	Ir 194		3x10- (4)
Iron (26)	Fe 55		8x10- (3)
	Fe 59		6x10- (6)
Krypton (36)	Kr 85m	1x10- (6)	
	Kr 85	3x10- (6)	
Lanthanum (57)	La 140		2x10- (4)
Lead (82)	Pb 203		4x10- (3)
Lutetium (71)	Lu 177		1x10- (3)
Manganese (25)	Mn 52		3x10- (4)
	Mn 54		1x10- (3)
	Mn 56		1x10- (3)
Mercury (80)	Hg 197m		2x10- (3)
	Hg 197		3x10- (3)
	Hg 203		2x10- (4)
Molybdenum (42)	Mo 99		2x10- (3)
Neodymium (60)	Nd 147		6x10- (4)
	Nd 149		3x10- (4)
Nickel (28)	Ni 65		1x10- (3)
Niobium (Columbium) (41)	Nb 95		1x10- (3)
	Nb 97		9x10- (3)
Osmium (76)	Os 185		7x10- (4)
	Os 191m		3x10- (2)
	Os 191		2x10- (3)
	Os 193		6x10- (4)
Palladium (46)	Pd 103		3x10- (3)

	Pd 109		9x10- (4)
Phosphorus (15)	P 32		2x10- (4)
Platinum (78)	Pt 191		1x10- (3)
	Pt 193m		1x10- (2)
	Pt 197m		1x10- (2)
	Pt 197		1x10- (8)
Polonium (84)	Po 210	2x10- (10)	7x10- (6)
Potassium (19)	K 42		3x10- (3)
Praseodymium (59)	Pr 142		3x10- (4)
	Pr 143		5x10- (4)
Promethium (61)	Pm 147		2x10- (3)
	Pm 149		4x10- (4)
Radium (88)	Ra 226	1x10- (11)	1x10- (7)
	Ra 228	2x10- (11)	3x10- (7)
Rhenium (75)	Re 183		6x10- (8)
	Re 186		9x10- (4)
	Re 188		6x10- (4)
Rhodium (45)	Rh 103m		1x10- (2)
	Rh 105		1x10- (3)
Rubidium (37)	Rb 86		7x10- (4)
Ruthenium (44)	Ru 97		4x10- (2)
	Ru 103		8x10- (4)
	Ru 105		1x10- (2)
	Ru 106		1x10- (4)
Samarium (62)	Sm 152		8x10- (4)
Scandium (21)	Sc 46		4x10- (4)
	Sc 47		9x10- (4)
	Sc 48		3x10- (4)
Selenium (34)	Se 75		3x10- (3)
Silicon (14)	Si 31		9x10- (3)
Silver (47)	Ag 105		1x10- (3)
	Ag 110m		3x10- (4)
	Ag 111		4x10- (4)
Sodium (11)	Na 24		2x10- (3)
Strontium (38)	Sr 85		1x10- (2)
	Sr 89		1x10- (4)
	Sr 91		7x10- (4)
	Sr 92		7x10- (4)
Sulfur (16)	S 35	9x10- (3)	6x10- (4)
Tantalum (73)	Ta 182		4x10- (4)
Technetium (52)	Tc 96m		1x10- (1)
	Tc 96		1x10- (3)
Tellurium (52)	Te 125m		2x10- (3)
	Te 127m		6x10- (4)
	Te 127		3x10- (3)
	Te 129m		3x10- (4)

	Te 131m		6x10- (4)
	Te 132		3x10- (4)
Terbium (65)	Tb 160		4x10- (4)
Thallium (81)	Tl 200		4x10- (3)
	Tl 201		3x10- (3)
	Tl 202		1x10- (3)
	Tl 204		1x10- (3)
Thulium (69)	Tm 170		5x10- (4)
	Tm 171		5x10- (3)
Tin (50)	Sn 113		9x10- (4)
	Sn 125		2x10- (4)
Tungsten (Wolfram) (74)	W 181		4x10- (3)
	W 187		7x10- (4)
Vanadium (23)	V 48		3x10- (4)
Xenon (54)	Xe 131m	4x10- (6)	
	Xe 133	3x10- (6)	
	Xe 135	1x10- (6)	
Ytterbium (70)	Yb 175		1x10- (3)
Yttrium (39)	Y 90		2x10- (4)
	Y 91m		3x10- (2)
	Y 91		3x10- (4)
	Y 92		6x10- (4)
	Y 93		3x10- (4)
Zinc (30)	Zn 65		1x10- (3)
	Zn 69m		7x10- (4)
	Zn 69		2x10 (2)
Zirconium (40)	Zr 95		6x10- (4)
	Zr 97		2x10- (4)
Beta and/or gamma emitting radioactive material not listed above with half-life less than 3 years.		1x10- (10)	1x10- (6)
Alpha emitting radioactive material (other than special nuclear material) not listed above.		1x10- (12)	1x10- (8)

(1)Values are given only for those radionuclides normally used as gases.
(2)uc/gm for solids.
Note 1: Many radionuclides disintegrate into daughter products which are also radioactive. In expressing the concentrations in Table 2 the activity stated is that of the parent radionuclide and takes into account the radioactive daughter products.

Note 2: For purposes of Table 1, subdivision (a), where there is present a combination of radionuclides, the limit for the combination shall be derived as follows: Determine for each radionuclide present the ratio between the concentration of the radionuclide in the combination and the exempt concentration listed in Table 2. The sum of such ratios shall not exceed unity.
Example:
(1)Values are given only for those radionuclides normally used as gases.
(2)uc/gm for solids.

Concentration of Radionuclide A in Combination/Exempt concentration of Radionuclide A + Concentration of Radionuclide B in Combination/Exempt concentration of Radionuclide B <= 1

Appendix B of Section 38.41 is amended as follows:

Atomic No. 38 Strontium-80, classes D and Y are amended by adding a "3" subscript after "SrTiO".

Atomic No. 42 Molybdenum-90, class Y is amended by adding a "2" subscript after "MoS".

Atomic No. 62 Samarium-146, class W in Table I, Col. 2 is changed from "4E2" to "4E-2".

Atomic No. 62 Samarium-147, class W in Table I, Col. 2 is changed from "4E2" to "4E-2".

Atomic no. 64 Gadolinium-148, class D in Table I, Col. 2 is changed from "2E+2" to "2E-2".

Atomic No. 68 Erbium-172, class W in Table I, Col. 1 is changed from "E+3" to "1E+3".

Atomic No. 75 Rhenium-187, class D is amended by moving "St wall" from Table I, Col. 1 to Table I, Col. 2.

Atomic No. 82 Lead-210, class D is amended by changing Table I, Col. 1 from "6E1" to "6E-1".

Atomic No. 82 Lead-210, class D is amended by changing Table I, Col. 2 from "2E1" to read "2E-1".

Atomic No. 92 Uranium-230, classes D, W, and Y are amended by adding the appropriate subscripts so as to read "D - UF_6, UO_2F_2, $UO_2(NO_3)_2$; W - UO_3, UF_4, UCl4; and Y - UO_2, U_2O_8".

Atomic No. 94 Plutonium-234, both classes W and Y are amended by adding the "2" subscript to PuO to read "PuO_2".

The third line of the next two entries below Atomic No. 101 Mendelevium-258 are amended by adding a hyphen (-) after "fis" so that the word fission is shown to be one word.

Note 2., (two paragraphs below the previous change) is amended by moving "1E-12" from Table II, Col. 2 to Table II, Col. 1.

"Footnotes to Ionizing Radiation Protection (Code Rule 38)" is amended to read as follows:

FOOTNOTES

TO

IONIZING RADIATION PROTECTION

(CODE RULE 38)

Footnotes A through M Material Incorporated By Reference. The documents referenced in this part are available for review and copying at the New York State Department of Labor, State Office Campus, Building 12, Room 509, Albany, New York or the New York State Department of State, 162 Washington Avenue, Albany, New York.