

## **Part 38. IONIZING RADIATION PROTECTION**

**(Statutory authority: Labor Law, §27; General Business Law, §483)**

**Historical** Part (§§38.0-38.41) repealed, new filed July 6, 1978; amd. filed June 25, 1985 eff.  
**Note:** June 25, 1985. Amended Part title.

### **§ 38.0 Finding of fact.**

The commissioner finds that every industry, trade, occupation and process involving the use or presence of radioactive material or radiation-producing equipment involves elements of danger to the lives, health and safety of persons employed or present therein. The commissioner further finds that special regulations are necessary for the protection of such persons, in that such material and equipment may emit invisible and imperceptible rays or particles having the property of producing deleterious or fatal effects, immediate or deferred, upon and within the human body.

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978 eff. July 10,  
**Note:** 1978.

§ 38.41 **Tables and appendices.** The tables (see Appendix A-10, *infra*) 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 9-Exempt Concentrations,](#)

[Appendix A-12-A<sub>1</sub> and A<sub>2</sub> Values for Radionuclides,](#)

[Appendix A-13-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-2-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 (rule).

**Historical Note:** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; amds. filed June 25, 1985; Feb. 19, 1991; March 15, 1993; repealed, new filed June 9, 1994; amd. Filed April 15, 1999 eff. May 5, 1999.

**§ 38.40 Severability.**

If any provision of this Part (rule) or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of this Part (rule) which can be given effect without the invalid provisions or applications, and to this end the provisions of this Part (rule) are declared to be severable.

**Historical Note:** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978 eff. July 10, 1978.

**§ 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 five 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<sup>1</sup>.

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; amds. filed:  
**Note:** June 25, 1985; March 15, 1993; repealed, filed June 9, 1994; new filed April 15, 1999 eff. May 15, 1999.

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<sup>1</sup>The documents referenced in this Part are available for review and copying at the Department of Labor State Campus, Bldg. 12, Rm. 509, Albany, NY or the Department of State, 41 State St., Albany, NY.

**§ 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; and

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

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

\* 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 Distributed 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 30th, and be filed by July 31st 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 (1) 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.

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

(a) 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 subdivision;

(b) 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

(c) 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 the table.\*

(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 one 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

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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) 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 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”;

(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;

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

(c) The report must cover the period between the filing of the preceding report and the occurrences specified in subclause (b)(1) or (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 38.3 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 Section 38.18 (a)(1) 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

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(Name of Manufacturer or Distributor)\*

-OR-

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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) 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

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(Name of Manufacturer or Distributor)\*

(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.

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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.

(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 section 38.18(a)(1) 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 subdivision; 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<sup>1</sup>.

(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) of this subdivision, 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 USNRC 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

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(Name of manufacturer, assembler, or initial transferor.)\*

(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 subdivision, 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;

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<sup>1</sup> The documents referenced in this Part are available for review and copying at the Department of Labor, State Campus, Building. 12, Rm. 509, Albany, N.Y. or the Department of State, 41 State St., Albany, N.Y.

\*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.

(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; and
- (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<sup>1</sup>, 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 one 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 five 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 subclause (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 subdivision 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

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(Name of manufacturer or initial transferor)

(3) Leak testing of each source.

(i) Each person licensed under this subdivision 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.

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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.

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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<sup>1</sup>; and

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

(2) Quality Assurance:

(i) Each person licensed under this subdivision 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 subdivision 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 subdivision 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<sup>1</sup>, 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 one inch of mercury. Lowered pressure shall be maintained for one 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.

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<sup>1</sup> The documents referenced in this part are available for review and copying at the Department of Labor, State Campus, Bldg. 12, Rm. 509, Albany, NY or the Department of State, 41 State St., Albany, NY.

(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 subdivision 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<sup>1</sup>, 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 subdivision.

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

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<sup>1</sup>The documents referenced in this part are available for review and copying at the Department of Labor, State Campus, Bldg. 12, Rm. 509, Albany, NY or the Department of State, 41 State St., Albany, NY.

(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 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 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, 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; 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.

(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.

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; repealed, filed  
**Note:** June 9, 1994; new filed April 15, 1999 eff. May 5, 1999.

### **§ 38.34 Additional requirements for industrial radiography.**

(a) Definitions. As used in this section the following terms have these defined meanings:

- (1) "Associated equipment"-equipment used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides or comes in contact with the source, (i.e., guide tube, control tube, crank, removable source stop, "J" tube).
- (2) "Collimator"-a device used to limit the size, shape, and direction of the primary radiation beam.
- (3) "Control (crank-out) device"-the control cable, the protective sheath and control drive mechanism used to move the sealed source from its shielded position in the radiographic device or camera to an unshielded position outside the device for the purpose of making a radiographic exposure.
- (4) "Control tube"-protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.
- (5) "Exposure head"-a device that locates the gamma radiography sealed source.
- (6) "Field examination"-a demonstration of practical application of the principles learned in the classroom that should include use of all appropriate equipment and procedures.
- (7) "Periodic training"-a periodic review conducted or provided by the licensee for its employees on radiation safety aspects of radiography. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, accidents or errors that have been observed, and opportunities for employees to ask safety questions.
- (8) "Permanent radiographic installation"-an enclosed shielded room, cell, or vault in which radiography is performed.
- (9) "Projection sheath (guide tube)"-a flexible or rigid tube (i.e., "J" tube) for guiding the source assembly and the attached control cable from the exposure device to the exposure head or working position.
- (10) "Radiographer"-any individual who has successfully completed the training and testing requirements specified in this section for radiographers, and who conducts or personally supervises radiographic operations at a site.

(11) "Radiographer's assistant"-any individual who has successfully completed the training and testing requirements specified in this section for a radiographer's assistant, and who must use radiographic exposure devices, sealed sources or related handling tools, or radiation survey instruments under the personal supervision of a radiographer.

(12) "Radiographic exposure device"-any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making radiographic exposure, (i.e., a camera, or a projector).

(13) "Radiography"-the examination of the structure of materials by nondestructive methods, utilizing sealed sources of radioactive materials.

(14) "Sealed source"-any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

(15) "Shielded position"-the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement. (In this position the radiation exposure will be at a minimum. This position incorporates maximum shielding for the radioactive source.)

(16) "Source assembly"-consists of the sealed source and a connector. May also include a stop ball used to secure the source in the shielded position. The connector attaches to the control cable.

(17) "Source changer"-a device designed and used for replacement of sealed sources in radiographic exposure devices, including those also used for transporting and storage of sealed sources.

(18) "Storage area"-any location, facility, or vehicle which is used to store or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use; and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.

(19) "Storage container"-a device in which sealed sources are stored.

(20) "Temporary jobsite"-a place where licensed materials are present for the purpose of performing radiography, other than any permanent radiographic installation.

(b) Equipment. Equipment used in industrial radiographic operations must meet the following minimum criteria:

(1) Each radiographic exposure device and all associated equipment must meet the requirements specified in American National Standard N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography", NBS Handbook 136, US Department of Commerce.<sup>4</sup>

(2) In addition to the requirements specified in paragraph (1) of this subdivision, the following requirements apply to radiographic exposure devices and associated equipment.

(i) Each radiographic exposure device must have attached to it by the user, a durable, legible, clearly visible label bearing the:

(a) chemical symbol and mass number of the radionuclide in the device;

(b) activity and the date on which this activity was last measured;

(c) model number and serial number of the sealed source;

(d) manufacturer of the sealed source; and

(e) licensee's name, address, and telephone number.

(ii) Radiographic exposure devices intended for use as Type B transport containers must meet applicable requirements of 10 Code of Federal Regulations, Part 71 , 1994 edition.<sup>5</sup>

(iii) Modification of any exposure devices and associated equipment is prohibited.

(3) In addition to the requirements specified in paragraphs (1) and (2) of this subdivision, the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for routine operation.

(i) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

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<sup>4&5</sup> 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, N.Y. or the New York State Department of State, 162 Washington Avenue, Albany, N.Y.

(ii) The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

(iii) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

(iv) Each sealed source or source assembly must have attached to it or engraved on it, a durable, legible, visible label with the words: "DANGER-RADIOACTIVE. " The label must not interfere with the safe operation of the exposure device or associated equipment.

(v) Guide tubes must be used when moving the source out of the device.

(vi) The guide must have passed the crushing tests for the control tube as specified in ANSI N432 and a kinking resistance test that closely approximates the kinking forces likely to be encountered during use.

(vii) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during radiographic operations.

(viii) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432.

(ix) Source changers must provide a system for assuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

(4) All newly manufactured radiographic exposure devices and associated equipment acquired by licensees after January 10, 1992 must comply with the requirements of this section.

(5) All radiographic exposure devices, source assemblies, and associated equipment in use after January 10, 1996 must comply with the requirements of this section.

(6) All associated equipment acquired after January 10, 1996 must be labelled to identify that the components have met the requirements of this section.

(c) Limits on levels of radiation for radiographic exposure devices, storage containers, and source changes.

- (1)
  - (i) Radiographic exposure devices measuring less than 10 centimeters (four inches) from the sealed source storage position to any exterior surface of the device shall have no radiation level in excess of 0.5 millisieverts (50 millirems) per hour at 15 centimeters (six inches) from any exterior surface of the device.
  - (ii) Radiographic exposure devices measuring a minimum of 10 centimeters (four inches) from the sealed source storage position to any exterior surface of the device, and all storage containers for sealed sources or for radiographic exposure devices, shall have no radiation level in excess of 2 millisieverts (200 millirems) per hour at any exterior surface, and 0.1 millisieverts (10 millirems) per hour at one meter from any exterior surface. The radiation levels specified are with the sealed source in the shielded (i.e., "off") position.

(2) Paragraph (1) of this subdivision applies to all equipment manufactured prior to January 10, 1992. After January 10, 1996, radiographic equipment other than storage containers and source changers must meet the requirements of subdivision (b) of this section, and subdivision (c) of this section applies only to storage containers.

(d) Locking and relocation of radiographic exposure devices, storage containers, and source changers.

(1) Locked radiographic exposure devices and storage containers shall be physically secured to prevent tampering.

(i) Each radiographic exposure device shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device or its container shall be kept locked, (and if a keyed lock, with the key removed at all times), when not under the direct surveillance of a radiographer or a radiographer's assistant or as otherwise may be authorized in subdivision (p) of this section. In addition, during radiographic operations the sealed source assembly shall be manually secured in the shielded position each time the source is returned to that position, in those exposure devices manufactured prior to January 10, 1992.

(ii) Each sealed source storage container and source changer shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers shall be kept locked when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

(2) Radiographic exposure devices, source changers, and storage containers, prior to being moved from one location to another, shall be disassembled, safety plugs or covers applied, locked and physically secured to prevent accidental loss, tampering or removal of licensed material; and shall be surveyed to assure that the sealed source is in the shielded position before being moved.

(e) Radiation survey instruments.

(1) The licensee shall keep sufficient calibrated and operable radiation survey instruments at each temporary jobsite to make the radiation surveys required by this Part (rule). Instrumentation required by this section shall have a range such that 0.02 millisieverts (2 millirems) per hour through 0.01 Sievert (1 rem) per hour can be measured. Survey instruments shall be checked for operability prior to use. This may be accomplished by evaluating the instrument response to the previously measured fields at the projection sheath port or the control cable sheath port on a radiographic exposure device.

(2) The licensee shall have each radiation survey instrument required under paragraph (1) of this subdivision calibrated:

(i) at intervals not to exceed six months and after instrument servicing, except for battery changes;

(ii) for linear scale instruments, at two points located approximately 1/3 and 2/3 of full- scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two points of at least one decade; and for digital instruments, at appropriate points; and

(iii) so that an accuracy within plus or minus 20 percent of the calibration standard can be demonstrated on each scale.

(3) The licensee shall maintain records of the results of the instrument calibrations in accordance with subdivision (u) of this section

(f) Leak testing and replacement of sealed sources.

(1) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source, shall be performed only by persons specifically authorized by an Agreement State or the United States Nuclear Regulatory Commission to do so.

(2) Testing and recordkeeping requirements.

(i) Each licensee who uses a sealed source shall have the source tested for leakage at intervals not to exceed six months.

(ii) The licensee shall maintain records of the leak tests in accordance with subdivision (v) of this section.

(iii) In the absence of a certificate from the transferor that a test has been made within the six months before the transfer, the sealed source may not be used until tested.

(3) Method of testing. The wipe of a sealed source must be performed using a leak test kit or method approved by an Agreement State or the United States Nuclear Regulatory Commission, and must be analyzed by a person or company so approved. The wipe sample must be taken from the nearest accessible point to the sealed source where contamination might accumulate.

(4) Any test conducted pursuant to paragraphs (2) and (3) of this subdivision which reveals the presence of 185 Bq (0.005 microcuries) or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of, in accordance with this Part (rule). A report shall also be filed, within five days of the test, with the Department.

(g) Quarterly inventory.

(1) Each radiography licensee shall conduct a quarterly physical inventory to account for all sealed sources received and possessed under a license.

(2) The licensee shall maintain records of the quarterly inventory in accordance with subdivision (w) of this section.

(h) Inspection and maintenance of radiographic exposure devices, storage containers, associated equipment, and source changers.

(1) The licensee shall visually check for obvious defects in radiographic exposure devices, storage containers, associated equipment, and source changers prior to use each day the equipment is used to ensure that the equipment is in good working condition and that required labeling is present. If defects are found, the equipment must be removed from service until repaired, and a record must be made in accordance with subdivision (y) of this section.

(2) Each licensee shall have a program for inspection and routine maintenance of radiographic exposure devices, source changers, associated equipment and storage containers prior to the first use and at intervals not to exceed three months thereafter to ensure the proper functioning of components important to safety. If defects are found, the equipment must be removed from service until repaired. Records of such inspection, maintenance, removal from service and repair must be made in accordance with subdivision (y) of this section.

(3) Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration shall be periodically tested for depleted uranium contamination. This test could be performed by the licensee using available test kits or the exposure device could be returned to the manufacturer for such testing. This test shall be undertaken at intervals not to exceed 12 months and should such testing reveal the presence of DU contamination, the exposure device must be removed from use and arrangements for proper disposal in accordance with this Part (rule) must be made.

(i) Permanent radiographic installations.

(1) Permanent radiographic installations shall have high radiation area entrance controls of the types described in section 38.25(d) of this Part (rule), and shall also meet the following special requirements.

(2) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation to which this section applies shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be actuated by radiation whenever the source is exposed. The audible signal shall be actuated when an attempt is made to enter the installation while the source is exposed.

(3) The alarm system must be tested for proper operation at intervals not to exceed three months and the beginning of each day of equipment use. The daily test shall include a check of the visible and audible signals by a crank out of the exposure device prior to use of the room. If a control device or alarm is operating improperly, it shall be immediately labeled as defective and repaired before industrial radiographic operations are resumed. Test records shall be maintained in accordance with subdivision (z) of this section.

(j) Labels, storage, and transportation precautions.

(1) Labels.

(i) The licensee may not use a source changer or container to store licensed material unless the source changer or the container has securely attached to it a durable, legible, and clearly visible label. The label must contain the radiation symbol specified in section 38.25 of this Part (rule) and the wording "CAUTION (OR DANGER) RADIOACTIVE MATERIAL-DO NOT HANDLE, NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)".

(ii) The licensee may not transport licensed material unless the material is packaged, labeled, marked, and accompanied with appropriate shipping papers in accordance with the requirements of section 38.31 of this Part (rule).

(2) Security precautions during storage and transportation.

(i) Locked radiographic exposure devices and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store licensed material in a manner which will minimize danger from explosion or fire.

(ii) The licensee shall lock and physically secure the transport package containing licensed material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the licensed material from the vehicle.

(k) Radiation safety officer. The radiation safety officer (RSO) shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's program.

(1) The RSO's qualification shall include:

(i) completion of the training and testing requirements of paragraph (l)(1) of this section; and

(ii) two years of documented experience in industrial radiographic operations, with at least 40 hours of formal classroom training with respect to the oversight of radiation protection programs.

(2) The specific duties of the RSO include, but are not limited to, the following:

(i) to establish and oversee operating, emergency, and ALARA procedures, and to review them regularly to ensure that the procedures are current and conform with these rules;

(ii) to oversee and approve all phases of the training program for radiographic personnel so that appropriate and effective radiation protection practices are taught;

(iii) to ensure that required radiation surveys and leak tests are performed and documented in accordance with these rules, including any corrective measures when levels of radiation exceed established limits;

(iv) to ensure that personnel monitoring devices are calibrated and used properly by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by section 38.29 of this Part (rule); and

(v) to ensure that operations are conducted safely and to assume control and have the authority to institute corrective actions, including stopping of operations, when necessary in emergency situations or unsafe conditions.

(l) Training.

(1) The licensee shall not permit any individual to act as radiographer until such individual:

(i) has been instructed in the subjects outlined in paragraph (6) of this subdivision;

(ii) has received copies of, and instruction in, regulations contained in this Part; in the license under which the radiographer will perform radiography, and the licensee's operating and emergency procedures;

(iii) has demonstrated competence to use the licensee's radiographic exposure devices, sealed sources, related handling tools, and survey instruments; and

(iv) has demonstrated understanding of the instructions in this paragraph by successful completion of a written test and a field examination on the subjects covered in paragraph (6) of this subdivision.

(2) The licensee shall not permit any individual to act as a radiographer's assistant until such individual:

(i) has received copies of and instruction in regulations contained in this Part, in the license under which the assistant radiographer will work, and the licensee's operating and emergency procedures;

(ii) has demonstrated competence to use, under the personal supervision of the radiographer, the radiographic exposure devices, sealed sources, related handling tools, and radiation survey instruments that the assistant will use; and

(iii) has demonstrated understanding of the instructions in this paragraph by successfully completing a written or oral test and a field examination on the subjects covered.

(3) The licensee shall provide periodic training for radiographers and radiographer's assistants at least once during each calendar year.

(4) The licensee shall conduct a semi-annual inspection program of the job performance of each radiographer and radiographer's assistant to ensure that these regulations, license requirements, and the applicant's operating and emergency procedures are followed. The inspection program must:

(i) include observation of the performance of each radiographer and radiographer's assistant during an actual radiographic operation at intervals not to exceed six months; and

(ii) provide that, if a radiographer or a radiographer's assistant has not participated in a radiographic operation for more than three months since the last inspection, that individual's performance must be observed and recorded the next time the individual participates in a radiographic operation.

(5) The licensee shall maintain records of the above training; to include written, oral, and field examinations, periodic training, and semi-annual inspections of job performance in accordance with subdivision (aa) of this section.

(6) The licensee shall include the following subjects in the training required in subparagraph (1)(i) of this subdivision:

(i) fundamentals of radiation safety including:

- (a) characteristics of gamma radiation;
- (b) units of radiation dose and quantity of radioactivity;
- (c) hazards of exposure to radiation;
- (d) levels of radiation from licensed material; and
- (e) methods of controlling radiation dose (time, distance, and shielding);

(ii) radiation detection instruments including:

- (a) use, operation, calibration, and limitations of radiation survey instruments;
- (b) survey techniques; and
- (c) use of personnel monitoring equipment;

(iii) equipment to be used including:

- (a) operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtailed);
- (b) storage, control, and disposal of licensed material; and
- (c) maintenance of equipment;

(iv) the requirements of this Part (rule) and of pertinent Federal regulations; and

(v) case histories of accidents in radiography.

(m) Operating and emergency procedures.

(1) Operating and emergency procedures must include instructions in at least the following:

- (i) the handling and use of licensed sealed sources and radiographic exposure devices to be employed, such that no person is likely to be exposed to radiation doses in excess of the limits established in this Part (rule);
- (ii) methods and occasions for conducting radiation surveys;
- (iii) methods for controlling access to radiographic areas;

(iv) methods and occasions for locking and securing radiographic exposure devices, storage containers and sealed sources;

(v) personnel monitoring and the use of personnel monitoring equipment;

(vi) transporting sealed sources to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when needed, and control of the sealed sources during transportation;

(vii) the inspection and maintenance of radiographic exposure devices and storage containers;

(viii) steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale;

(ix) the procedure(s) for identifying and reporting equipment malfunction, as required by section 38.29(b)(2)(iii) of this Part (rule).

(x) the procedure for notifying proper persons in the event of an accident;

(xi) minimizing exposure of persons in the event of an accident;

(xii) source recovery procedure if licensee will perform source recovery; and

(xiii) form of records.

(2) The licensee shall maintain copies of current operating and emergency procedures in accordance with subdivision (bb) of this section.

(n) Personnel monitoring.

(1) The licensee shall not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each such individual wears a direct reading pocket dosimeter, an alarm ratemeter, and either a film badge or a thermoluminescent dosimeter (TLD) except that for permanent radiography facilities where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required. Pocket dosimeters shall have a range from zero to 2 millisieverts (200 millirems) and shall be recharged at the start of each shift. In cases where the exposure will be greater than 2 millisieverts (200 millirems) an exemption must be applied for to use a pocket dosimeter with a higher endpoint. Each film badge and TLD shall be assigned to and worn by only one individual. Film badges and TLDs must be replaced at least monthly. After replacement, each film badge or TLD must be promptly processed.

(2) Pocket dosimeters must be read and the exposures recorded at the beginning and end of each shift, and records shall be maintained in accordance with subdivision (cc) of this section.

(3) Pocket dosimeters shall be checked at periods not to exceed 12 months for correct response to radiation, and records shall be maintained in accordance with subdivision (cc) of this section. Acceptable dosimeters shall read within plus or minus 30 percent of the true radiation exposure.

(4) If an individual's pocket dosimeter is found to be off scale, and the possibility of radiation exposure cannot be ruled out as the cause, his/her film badge or TLD shall be immediately sent for processing. In addition, the individual shall not work with licensed material until a determination of his/her radiation exposure has been made. This determination shall be made by the RSO or his/her designee. The results of this determination must be included in the records maintained in accordance with subdivision (cc) of this section.

(5) If a film badge or TLD is lost or damaged, the worker shall cease work immediately until a replacement film badge or TLD is provided and the exposure is calculated for the time period from issuance to loss or damage of the film badge or TLD.

(6) Reports received from the film badge or TLD processor must be retained in accordance with subdivision (cc) of this section.

(7) Each alarm ratemeter must:

(i) be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each shift;

(ii) be set to give an alarm signal at a preset dose rate of 5 mSv/hr (500 mrem/hr); with an accuracy of plus or minus 20 percent of the true radiation dose rate;

(iii) require special means to change the preset alarm function;

(iv) have the alarm function turned "on" at all times during radiographic operations; and

(v) be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee shall maintain records of alarm ratemeter calibrations in accordance with subdivision (cc) of this section.

(o) Radiation surveys. The licensee shall:

(1) Maintain at least one calibrated and operable radiation survey instrument that meets the requirements of subdivision (e) of this section at each location of its radiographic operations whenever radiographic operations are being performed, including a source exchange; and at the storage area, as defined in subdivision (a) of this section, whenever a radiographic exposure device, a storage container, or source is being placed in storage.

(2) Conduct a survey of the camera with a radiation survey instrument after each exposure to determine that the sealed source has been returned to its shielded position.

(3) Conduct a survey of the source guide tube to determine that the source has been returned to its shielded position prior to exchanging films, repositioning the collimator, or dismantling equipment.

(4) Conduct a survey with a radiation survey instrument any time the source is exchanged and whenever a radiographic exposure device is placed in a storage area, as defined in subdivision (a) of this section to determine that the sealed source is in its shielded position.

(5) For recordkeeping requirements see subdivision (dd) of this section.

(p) Security. During each radiographic operation the radiographer or radiographer's assistant shall maintain a continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in this Part (rule), except:

(1) where the high radiation area is equipped with a control device or an alarm system as described in section 38.25(d) of this Part (rule); or

(2) where the high radiation area is locked to protect against unauthorized or accidental entry.

(q) Posting. Notwithstanding any provisions in section 38.25(b)(2) of this Part (rule), areas in which radiography is being performed shall be conspicuously posted as required by section 38.25 (b)(1) of this Part (rule).

(r) Supervision of radiographers' assistants. Whenever a radiographer's assistant uses radiographic exposure devices, uses sealed sources or related source handling tools, or conducts radiation surveys required by paragraph (o)(2) of this section to determine that the sealed source has returned to the shielded position after an exposure, the assistant shall be under the personal supervision of a radiographer. The personal supervision shall include:

(1) the radiographer's personal presence at the site where the sealed sources are being used;

(2) the ability of the radiographer to give immediate assistance if required; and

(3) the radiographer's watching the assistant's performance of the operations referred to in this section.

(s) Requirements for radiographic operations conducted outside of a permanent radiographic installation. Whenever radiography will be performed outside of a permanent radiographic installation the radiographer must be accompanied by another qualified radiographer, or an individual with at least the qualifications of a radiographer's assistant, who is observing the operations and is capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

(t) Records of receipt and transfer of sealed sources.

(1) Each licensee shall maintain records showing the receipts and transfers of sealed sources.

(2) These records shall include the date, the individual making the record, the radionuclide, number of curies, and make, model, and serial number of each sealed source and device, as appropriate.

(3) The licensee shall retain the records required by paragraph (1) of this subdivision for three years after the record is made.

(u) Records of radiation survey instruments.

(1) Each licensee shall maintain records of the calibrations of their radiation survey instruments.

(2) The licensee shall retain the records required by paragraph (1) of this subdivision for three years after the record is made.

(v) Records of leak testing and replacement of sealed sources.

(1) Each licensee shall maintain records of leak test results in units of becquerels (curies).

(2) The licensee shall retain the records required by paragraph (1) of this subdivision for three years after the record is made.

(w) Records of quarterly inventory.

(1) Each licensee shall maintain records of the quarterly inventory.

(2) The record shall include the quantities and kinds of radioactive material (including the model number, the serial number and manufacturer), location of sealed sources, the name of the individual conducting the inventory, and the date of the inventory.

(3) The licensee shall retain the records required by paragraph (1) of this subdivision for three years after the record is made.

(x) Utilization logs.

(1) Each licensee shall maintain current utilization logs at the address specified in the license, showing for each sealed source the following information:

(i) a description, including the make, model number, and serial number of the radiographic exposure device or storage container in which the sealed source is located;

(ii) the identity and signature of the radiographer to whom assigned; and

(iii) the plant or site where used and dates of use, including the dates removed and returned to storage.

(2) The licensee shall retain the logs required by paragraph (1) of this subdivision for three years after the log is made.

(y) Records of inspection and maintenance of radiographic exposure devices, storage containers, associated equipment, and source changers.

(1) Each licensee shall maintain records of inspection and maintenance of radiographic exposure devices, storage containers, associated equipment, and source changers.

(2) The record shall include the date of check, name of inspector, equipment involved, any defects found, and repairs made.

(3) The licensee shall retain the records required by paragraph (1) of this subdivision for three years after the record is made.

(z) Records of permanent radiographic installations.

(1) Each licensee shall maintain records of alarm system tests.

(2) The licensee shall retain the records required by paragraph (1) of this subdivision for three years after the record is made.

(aa) Records of training.

(1) Each licensee shall maintain records of training of each radiographer and each radiographer's assistant, to include copies of written tests, dates of oral tests, and field examinations.

(2) Each licensee shall maintain records of periodic training for each radiographer and each radiographer's assistant. The records must list the topics discussed, the dates of the reviews, and the attendees.

(3) The licensee shall retain the records required by paragraphs (1) and (2) of this subdivision for three years after the record is made.

(bb) Copies of operating and emergency procedures.

(1) Each licensee shall maintain a copy of current operating and emergency procedures.

(2) The licensee shall retain the records until the commissioner terminates the license.

(3) If procedures are superseded, the licensee shall retain the superseded material for three years after each change.

(cc) Records of personnel monitoring.

(1) Each licensee shall maintain records of daily exposures recorded from pocket dosimeter readings, and of yearly checks for correct dosimeter response to radiation within plus or minus 30 percent of true radiation exposure.

(2) The licensee shall retain the records required by paragraph (1) of this subdivision for three years after the record is made.

(3) Each licensee shall maintain records of reports received from the film badge or TLD processor.

(4) The licensee shall retain the records required by paragraph (3) until the commissioner terminates the license.

(5) Each licensee shall maintain records of the calibrations of alarm ratemeters for three years after the record is made.

(dd) Records of radiation surveys.

(1) Each licensee shall maintain records of the survey of a radiographic exposure device and source guide tube after the last exposure of the work day, after any source exchange, and whenever a device is placed in a storage area.

(2) The licensee shall retain the records required by paragraph (1) of this subdivision for three years after the record is made.

(ee) Form of records. Each record required by this Part (rule) must be legible throughout the specified retention period. The record may be the original or a reproduced copy, or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention

period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(ff) Location of records. All records required by this Part (rule) must be maintained for inspection at the address listed on the license. However, if this address is not located within New York State the licensee shall, at the request of the commissioner, bring such records as pertain to use of radiation sources in New York State, to such location within the state as the commissioner may direct for the purpose of inspection.

(gg) Documents required at temporary jobsites. Each licensee conducting operations at a temporary jobsite shall maintain copies of the following documents and records at the temporary jobsite until the radiographic operation is completed:

- (1) operating and emergency procedures required by subdivision (m) of this section;
- (2) evidence of latest calibration of the radiation survey instruments in use at the site required by subdivision (u) of this section;
- (3) the latest survey records, required by subdivision (dd) of this section;
- (4) the shipping papers for the transportation of radioactive materials; and
- (5) when operating under reciprocity pursuant to section 38.15 of this Part (rule), a copy of the license authorizing use of licensed materials.

(hh) Notification of incidents.

(1) In addition to the reporting requirements specified in section 38.29 of this Part (rule), each licensee shall provide a written report to the commissioner of the occurrence of any of the following incidents involving radiographic equipment:

- (i) unintentional disconnection of the source assembly from the control cable;
- (ii) inability to retract the source assembly to its full shielded position and secure it in this position;
- (iii) failure of any component (critical to safe operation of the device) to properly perform its intended function.

(2) The licensee shall include the following information in each report submitted under paragraph (1) of this subdivision, and in each report of overexposure submitted under section 38.29 (c) of this Part (rule) which involve failure of safety components of radiography equipment:

- (i) a description of the equipment problem;
- (ii) cause of each incident, if known;

- (iii) manufacturer and model number of equipment involved in the incident;
- (iv) place, time and date of the incident;
- (v) actions taken to establish normal operations;
- (vi) corrective actions taken or planned to prevent recurrence; and
- (vii) qualifications of personnel involved in the incident.

**§ 38.33 Specific requirements for well-logging operations.**

(a) Purpose. The requirements of this section are established for persons conducting well-logging operations in New York State. The requirements of this section are in addition to, and not in substitution of, other requirements of this Part (rule).

(b) Specific requirements. Each person conducting well-logging operations shall comply with the provisions of Part 39 of Title 10 of the Code of Federal Regulations, "Licenses and Radiation Safety Requirements for Well-Logging"; July 1, 1993 edition.<sup>3</sup>

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed: July 6, 1978; June 9, 1994 eff.

**Note:** June 29, 1994.

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<sup>3</sup> 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, N.Y. or the New York State Department of State, 162 Washington Avenue, Albany, N.Y.

**§ 38.32 Procedures for picking up, receiving, and opening packages.**

(a) Each licensee who expects to receive a package containing quantities of radioactive material in excess of the applicable A1 or A2 value specified in Appendix A-12, Table 1 of section 38.41 of this Part (rule), shall make arrangements to:

(1) receive the package when the carrier offers it for delivery; or

(2) receive notification of the arrival of the package at the carrier's terminal and to pick up the package expeditiously.

(b) Each licensee, upon receipt of a package containing radioactive material in quantities described in subdivision (a) of this section, or any package that shows evidence of damage or leakage shall monitor the external surfaces of the package for radioactive contamination and radiation levels. The licensee shall perform the monitoring as soon as practical after receipt of the package, but not later than three hours after the package is received during the licensee's normal working hours, or not later than three hours from the beginning of the next working day if it is received after working hours.

(c) Upon receipt of a package marked as containing radioactive material, and in a quantity equal to or less than the applicable A1 or A2 quantity, each licensee shall:

(1) survey each package for radiation levels; and

(2) monitor the package surface for radioactive contamination, unless the shipper of the package provides documentation of monitoring for radioactive contamination immediately prior to shipment demonstrating the absence of contamination.

(3) the licensee shall perform the monitoring required by this subdivision as soon as practical after receipt of the package, but not later than three hours after the package is received during normal working hours, or not later than three hours from the beginning of the next working day if it is received after working hours.

(d) The licensee shall immediately notify the final delivery carrier and the commissioner if packages are found to have any of the conditions in paragraphs (1) and (2) of this subdivision. Notification to the commissioner shall be made by telephone as well as by telegram, mailgram or facsimile.

(1) (i) Removable radioactive contamination in excess of 10 picocuries (22 dpm, or 370 mBq) per square centimeter on the external surfaces of the package for beta/gamma emitters, radionuclides with half lives less than 10 days, natural uranium and thorium, U-235, U-238, Th-232, or Th-228 and Th-230 in ores; and one picocurie (2.2 dpm, or 37 mBq) per square centimeter for all other alpha emitting radionuclides; all such contamination is to be averaged over 300 square centimeters;

(ii) For exclusive use shipments, removable contamination in excess of ten times the limit specified in subparagraph (i) of this paragraph.

(2) (i) Radiation levels at one meter from the external surface of the package in excess of 10 millirem (0.1 mSv) per hour, or radiation levels at the surface of the package in excess of 200 millirem (2 mSv) per hour;

(ii) For exclusive use shipments, a radiation level in excess of 1000 millirem (10 mSv) per hour at the package surface.

(e) Each licensee shall:

(1) establish and maintain written procedures for the safe opening of packages in which radioactive material is received that include consideration given to special instructions for the type of package being opened; and

(2) ensure that the procedures are followed.

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; amd. filed June 25, 1985; repealed, new filed June 9, 1994 eff. June 29, 1994  
**Note:**

### **§ 38.31 Transportation.**

(a) The transportation of radioactive materials is subject to other State and Federal requirements, particularly the following:

(1) New York State requirements. The Department of Transportation, Department of Motor Vehicles, certain public authorities and commissions as provided in the Vehicle and Traffic Law, and the requirements of cities having populations in excess of one million.

(2) Federal requirements. The United States Department of Transportation, the Nuclear Regulatory Commission, the Interstate Commerce Commission, the Federal Aviation Agency, the United States Coast Guard and, where the mails are used, the United States Postal Service.

(b) When the regulations of the New York State Department of Transportation, the United States Department of Transportation, the Nuclear Regulatory Commission or the Interstate Commerce Commission are not applicable to the shipment by land of radioactive materials by persons subject to the provisions of this Part (rule), such transportation shall, nevertheless, be in accordance with the requirements relating to the transportation of radioactive materials set forth in the regulations of the United States Department of Transportation, the Nuclear Regulatory Commission, the Interstate Commerce Commission and the New York State Department of Transportation. Any requests for modifications or exceptions to such requirements, any requests for special approvals referred to in such regulations, and any notifications referred to in such requirements shall be filed with, or made to, the commissioner.

(c) No person shall deliver radioactive material to a carrier or accept radioactive material from a carrier for transport, unless:

(1) the person has established procedures, prior to delivery of radioactive material to a carrier for transport, to ensure that the radioactive material is packaged and the package monitored in accordance with applicable New York State and the United States Department of Transportation and United States Nuclear Regulatory Commission regulations and has included on the package for the consignee, instructions to safely open the package when such instructions are appropriate; and

(2) the person has established procedures to ensure loading and unloading and monitoring of radioactive materials on a carrier's vehicle is done in compliance with applicable New York State and United States Department of Transportation and United States Nuclear Regulatory Commission regulations.

(3) the licensee shall perform the monitoring required by this subdivision as soon as practical after receipt of the package, but not later than three hours after the package is received during normal working hours, or not later than three hours from the beginning of the next working day if it is received after working hours.

(d) The transportation of radioactive materials by persons subject to the provisions of this Part (rule) shall also be subject to such additional requirements as the commissioner may order as reasonably appropriate and necessary to enforce the provisions of this Part (rule) relating to the general duty to protect health and safety.

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; amd. filed June 25, 1985; repealed, new added by renum. and amd. 38.39, filed June 9, 1994 eff. June 29, 1994.  
**Note:**

### **§ 38.30 Inspections-tests.**

Each person who possesses any radiation source shall comply with the following:

(a) Such person shall afford the commissioner an opportunity to inspect, at any reasonable time:

(1) the radiation source and the installation, institution, establishment, premises or facilities at which such source is located, possessed, stored or used; and

(2) each record required to be maintained by this Part (rule).

(b) Such person shall conduct, or permit the commissioner to conduct, such tests as he may require, including but not limited to tests of:

(1) any radiation source and the installation, institution, establishment, premises or facilities at which such radiation source is located, possessed, stored or used; and

(2) personnel monitoring equipment and any other equipment, instrument or device used in connection with the location, possession, storage or use of such radiation source.

(c) During the physical inspection of any installation or mobile source pursuant to this Part (rule), the commissioner or his representative shall permit a representative of the owner and a representative authorized by his employees to accompany him during such inspection for the purpose of aiding such inspection. Where there is no authorized employee representative, the commissioner or his representative may consult with a reasonable number of employees concerning health and safety matters pertinent to this Part (rule) in the installation or at the mobile source.

(d) Any employee or representative of employees who believes that a violation of this Part (rule) exists that threatens physical harm or radiation exposures in excess of the limits specified in this Part (rule), or that an imminent danger exists, may request an inspection by giving notice to the commissioner or his representative of such violation or danger. Any such notice may be reduced to writing, will set forth with reasonable particularity the grounds for the notice, and will be signed by the employee or representative of employees; and a copy will be provided the owner or his agent upon receipt or no later than at the time of inspection, except that, upon the request of the employee giving such notice, his name and names of individual employees referred to therein shall not appear in such copy or any record published, released, or made available by the commissioner or his representative. If, upon receipt of such notification, the commissioner or his representative determines there are reasonable grounds to believe that such violation or danger exists, he shall make a special inspection in accordance with the provisions of this Part (rule) as soon as practicable, to determine if such violation or danger exists.

(e) Prior to or during any inspection of an installation or mobile source subject to the requirements of this Part (rule), any employee or representative of employees employed in such installation or at the mobile source may notify the commissioner or his representative responsible for conducting the inspection, either orally or in writing, of any violation of this Part (rule) which he has reason to believe exists in such installation or at the mobile source. The commissioner or his representative shall review any action taken with respect to any such alleged violation and shall furnish the employee or representative of employees requesting such review a written statement of the reasons for the final disposition of the case.

(f) No person shall discharge or in any manner discriminate against any employee because such employee has filed any complaint or instituted or caused to be instituted any inspection or proceeding under this Part (rule), or has testified or is about to testify in any such proceeding, or because of the exercise by such employee on behalf of himself or others of any option afforded by this Part (rule).

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; amd. filed June 25, 1985; repealed, new added by renum. 38.38, filed June 9, 1994 eff. June 29, 1994.  
**Note:**

## § 38.29 Reports.

### (a) Reports of stolen, lost, or missing licensed or registered sources of radiation.

(1) Telephone reports. Each licensee or registrant shall report any stolen, lost or missing licensed or registered source of radiation to the commissioner by telephone immediately (as soon as possible but not more than four hours after discovery) after its occurrence becomes known.

(2) Written reports. Each licensee or registrant required to make a report pursuant to this subdivision shall, within 30 days after making the telephone report, make a written report to the commissioner setting forth the following information:

(i) a description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form, and for radiation equipment, the manufacturer, model and serial number, type and maximum energy of radiation emitted; and

(ii) a description of the circumstances under which the loss or theft occurred; and

(iii) a statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and

(iv) exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

(v) actions that have been taken, or will be taken, to recover the source of radiation; and

(vi) procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

(3) After filing the written report, the licensee or registrant shall also report any additional substantive information on the loss or theft within 30 days after the discovery of such information.

(4) The names of individuals who may have received exposure to radiation must be stated only in a separate and detachable portion of the report.

### (b) Notification of incidents.

(1) Immediate notification. Notwithstanding other requirements for notification, each licensee or registrant shall immediately (as soon as possible but not more than four hours after discovery) report each event involving a source of radiation possessed by

the licensee or registrant that may have caused or threatens to cause any of the following conditions:

(i) an individual to receive:

(a) a total effective dose equivalent of 0.25 Sv (25 rem) or more; or

(b) an eye dose equivalent of 0.75 Sv (75 rem) or more; or

(c) a shallow dose equivalent to the skin or extremities of 2.5 Gy (250 rad) or more; or

(d) a dose to any organ in which the total of the deep dose equivalent and the committed dose equivalent is 2.5 Sv (250 rem) or more; or

(ii) the release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures; or

(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.

(2) Twenty-four hour notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

(i) an individual to receive, in a period of 24 hours:

(a) a total effective dose equivalent exceeding 0.05 Sv (5 rem); or

(b) an eye dose equivalent exceeding 0.15 Sv (15 rem); or

(c) a shallow dose equivalent to the skin or extremities exceeding 0.5 Sv (50 rem); or

(d) a dose to any organ in which the total of the deep dose equivalent and the committed dose equivalent exceeds 0.5 Sv (50 rem); or

(ii) the release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures;

(iii) the following events involving licensed material:

(1) requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(2) involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix A-13 of section 38.41 of this Part (rule) for the material; and

(3) has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination;

(b) an event in which equipment is disabled or fails to function as designed when:

(1) the equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(2) the equipment is required to be available and operable at the time it is disabled or fails to function; and

(3) no redundant equipment is available and operable to perform the required safety function;

(c) an event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body;

(d) an unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(1) the quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix A-13 of section 38.41 of this Part (rule) for the material; and

(2) the damage affects the integrity of the licensed material or its container.

(3) The licensee or registrant shall prepare each report filed with the commissioner pursuant to this subdivision so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

(4) Licensees or registrants shall make the reports required by paragraphs (1) and (2) of this subdivision by telephone, telegram, mailgram, or facsimile to the commissioner and shall include the following information to the extent that it is available at the time of the report:

- (i) the reporting person's name and contact telephone number;
- (ii) a description of the event, including date and time;
- (iii) the exact location of the event;
- (iv) the radioactive materials involved, including quantities and chemical and physical form; and
- (v) any personnel radiation exposure data available.

(5) The provisions of this subdivision do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures, and are reported pursuant to subdivision (d) of this section.

(c) Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits.

(1) Reportable events. In addition to the notification required by subdivision (b) of this section, each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

- (i) incidents for which notification is required by subdivision (b) of this section;
- (ii) doses in excess of any of the following:
  - (a) the occupational dose limits for adults in section 38.18(a) of this Part (rule);
  - (b) the occupational dose limits for a minor in section 38.18(g) of this Part (rule);
  - (c) the limits for an embryo/fetus of a declared pregnant woman in section 38.18(h) of this Part (rule);
  - (d) the limits for an individual member of the public in section 38.19(a) of this Part (rule);

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

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

(iii) levels of radiation or concentrations of radioactive material in:

(a) a restricted area in excess of applicable limits in the license or registration;

(b) an unrestricted area in excess of 10 times the applicable limit set forth in this Part (rule) or in the license or registration, whether or not involving exposure of any individual in excess of the limits in section 38.19(a) of this Part (rule).

(2) Contents of reports.

(i) Each report required by this subdivision shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(a) a description of the incident or event, including the exact location, date and time, the probable cause, and a description of any equipment that failed or malfunctioned;

(b) estimates of each individual's dose; and

(c) the levels of radiation and concentrations of radioactive material involved; and

(d) the cause of any elevated exposures, dose rates, or concentrations; and

(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.

(ii) Each report filed pursuant to paragraph (1) of this subdivision shall include for each individual exposed: the name, social security account number, and date of birth. With respect to the limit for the embryo/fetus in section 38.18(h) of this Part (rule), the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

(3) All licensees or registrants who make reports pursuant to this subdivision shall submit the report in writing to the commissioner.

(d) Reports of planned special exposures. The licensee or registrant shall submit a written report to the commissioner within 30 days following any planned special exposure

conducted in accordance with section 38.18(f) of this Part (rule), informing the commissioner that a planned special exposure was conducted and indicating the date the exposure occurred and the information required by section 38.28(e) of this Part (rule).

(e) Notifications and reports to individuals.

(1) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in section 38.27 of this Part (rule).

(2) When a licensee or registrant is required pursuant to subdivision (c) of this section to report to the commissioner any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the commissioner, and shall comply with the provisions of section 38.27 of this Part (rule).

(f) Reports of leaking or contaminated sealed sources. If a sealed source is determined to be leaking or contaminated, a report shall be filed within five days with the commissioner describing the equipment involved, the test results and the corrective action taken.

(g) Reports of filing petitions for bankruptcy.

(1) Each holder of a specific and general license shall report immediately by certified mail to the commissioner following the filing of voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(i) the holder of a specific or general license,

(ii) an entity (i.e., person, estate, trust, governmental unit, or United States trustee) controlling the holder of a specific or general license or listing the license or holder thereof as property of the bankrupt estate; or

(iii) an affiliate (as defined in 11 USC section 101[2]) of the holder of a specific or general license.

(2) The bankruptcy notification shall indicate the:

(i) bankruptcy court in which the petition for bankruptcy was filed;

(ii) the date on which the petition was filed.

**Historical Note:** Sec. amd. filed June 10, 1971; repealed, new filed: July 6, 1978; June 9, 1994; amd. filed April 15, 1999 eff. May 5, 1999.

## § 38.28 Records.

### (a) General provisions.

(1) Each licensee or registrant shall use the SI units: becquerel, gray, sievert and coulomb per kilogram, or the special units: curie, rad, rem, and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this Part (rule).

(2) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this Part (rule): such as, total effective dose equivalent, shallow dose equivalent, eye dose equivalent, deep dose equivalent, or committed effective dose equivalent.

(3) Each record required by this Part (rule) shall be legible throughout the specified retention period and maintained in a form specified in this paragraph. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications shall include pertinent information, such as stamps, initials, and signatures. The licensee shall maintain safeguards sufficient to prevent tampering with and loss of records.

(4) The discontinuance of or curtailment of activities does not relieve any person who possesses any radiation source of responsibility for retaining all records required by this Part.

### (b) Records of radiation protection programs.

(1) Each licensee or registrant shall maintain records of the radiation protection program, including:

(i) the provisions of the program; and

ii) audits and other reviews of program content and implementation.

(2) The licensee or registrant shall retain the records required by subparagraph (1)(i) of this subdivision until the commissioner terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by subparagraph (1)(ii) of this subdivision for three years after the record is made.

### (c) Records of surveys, checks, tests and calibrations.

(1) Each licensee or registrant shall maintain records showing the results of surveys, checks, tests and calibrations required by this Part (rule).

(i) These records must show the date, the survey, check, test or calibration performed, the name of the individual performing the function, and the results.

(ii) The licensee or registrant shall retain these records for three years after the record is made.

(2) The licensee or registrant shall retain each of the following records until the commissioner terminates each pertinent license or registration requiring the record:

(i) records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and

(ii) records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

(iii) records showing the results of air sampling, surveys, and bioassays required pursuant to section 38.26 of this Part (rule); and

(iv) records of the results of measurements and calculations used to evaluate the release of radioactive effluents to unrestricted areas.

(3) Records of tests for leakage or contamination of sealed sources required by section 38.22 of this Part (rule) shall be kept in units of becquerels or microcuries and maintained for inspection by the commissioner.

(d) Records of prior occupational dose. The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in section 38.18 (e) of this Part (rule) on the department form for cumulative occupational radiation exposure history or equivalent until the 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.

(e) Records of planned special exposures.

(1) For each use of the provisions of section 38.18 (f) of this Part (rule) for planned special exposures, the licensee or registrant shall maintain records that describe:

(i) the exceptional circumstances requiring the use of a planned special exposure; and

(ii) the name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

(iii) what actions were necessary; and

(iv) why the actions were necessary; and

(v) what precautions were taken to assure that doses were maintained ALARA; and

(vi) what individual and collective doses were expected to result; and

(vii) the doses actually received in the planned special exposure.

(2) The licensee or registrant shall retain the records until the commissioner terminates each pertinent license or registration requiring the record.

(f) Records of individual monitoring results.

(1) Recordkeeping requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to section 38.24 of this Part (rule), and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before the effective date of this Part (rule) need not be changed. These records shall include, when applicable:

(i) the deep dose equivalent to the whole body, eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and

(ii) the estimated intake of radionuclides (see section 38.18[b] of this Part [rule]); and

(iii) the committed effective dose equivalent assigned to the intake of radionuclides; and

(iv) the specific information used to calculate the committed effective dose equivalent pursuant to section 38.18(d) of this Part (rule); and

(v) the total effective dose equivalent when required by section 38.18(b) of this Part (rule); and

(vi) the total of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest total dose.

(2) Recordkeeping frequency. The licensee or registrant shall make entries of the records specified in this subdivision at least annually.

(3) Recordkeeping format. The licensee or registrant shall maintain the records specified in this subdivision on the department form for occupational radiation exposure records for a monitoring period, or in clear and legible records containing all the information required by such form.

(4) The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception or the estimated age of the embryo/fetus in days or weeks as of the date of declaration, shall also be kept on file, but may be maintained separately from the dose records.

(5) The licensee or registrant shall retain each required form or record until the commissioner terminates each pertinent license or registration requiring the record.

(g) Records of dose to individual members of the public.

(1) Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public (see section 38.19[a] of this Part [rule]).

(2) The licensee or registrant shall retain the records required by this subdivision until the commissioner terminates each pertinent license or registration requiring the record.

(h) Records of transfer, receipt and disposition. Each licensee or registrant shall maintain records of each transfer, receipt and disposition of radioactive material. Such records shall be maintained for a period of three years after the records were made.

(i) Records necessary to eventual decommissioning.

(1) Each licensee shall maintain the following records:

(i) Records of spills or other occurrences involving the spread of contamination in and around the installation, equipment, or site. These records may be limited to instances when contamination remains after cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

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

(iii) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is required pursuant to section 38.7 of this Part (rule).

(2) Records of information important to the safe decommissioning of the installation shall be kept in an identified location until the license is terminated by the commissioner.

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed: July 6, 1978; June 9, 1994;

**Note:** amd. filed April 15, 1999 eff. May 5, 1999. Amended (d).

**§ 38.27 Notices, instructions and reports to workers.**

(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.

(b) Posting of notices to workers.

(1) Each licensee or registrant shall post current copies of the following documents:

(i) the regulations of this Part;

(ii) the radioactive materials license, and conditions or documents incorporated into the license by reference, and amendments thereto, or the certificate of registration;

(iii) the operating procedures (including emergency procedures) applicable to work under the license or registration; and

(iv) any notice of violation involving radiological working conditions, proposed imposition of civil penalty or order issued by the commissioner, and any response from the licensee or registrant.

(2) If posting of a document specified in paragraph (1) of this subdivision is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(3) A current copy of the notice to employees provided by the commissioner shall be posted by each licensee or registrant wherever individuals work in or frequent any portion of a controlled area.

(4) Documents, notices or forms posted pursuant to this section shall be conspicuous, be replaced if defaced or altered, and appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from assigned work locations to which the document applies.

(5) Department documents shall be posted within two working days after receipt of the documents from the commissioner; the licensee's or registrant's response, if any, shall be posted within two working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five working days or until action correcting violations, if any, has been completed, whichever is later.

(c) Instructions to workers.

(1) All individuals working in or frequenting any portion of a controlled area, or otherwise exposed to occupational doses of radiation, shall be:

(i) informed of the storage, transfer or use of radioactive material, of radiation-producing equipment or of radiation in such portions of the controlled area;

(ii) instructed in the operating procedures applicable to work under the license or registration and the health protection problems associated with exposure to such radioactive material or radiation, in precautions or procedures to minimize exposure, in the purposes and functions of protective devices employed, and required to demonstrate familiarity with such precautions, procedures and devices;

(iii) instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of this Part (rule) and the provisions of any license or registration for the protection of personnel from exposures to radiation or radioactive material occurring in such areas;

(iv) instructed in their responsibility to report promptly to the licensee or registrant any condition which may lead to or cause a violation of the commissioner's regulations or a license or registration, or cause unnecessary exposure to radiation or radioactive material;

(v) instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

(vi) advised as to the radiation exposure reports which workers must be given or may request pursuant to this Part (rule).

(2) The extent of these instructions shall be commensurate with potential radiological health problems in the controlled area, and instruction shall be given before an individual begins work in a controlled area and at least annually thereafter. Records documenting individual worker instruction shall be maintained for inspection by the commissioner for a period of three years.

(d) Notification and reports to individuals.

(1) Radiation exposure data for an individual for whom monitoring is required pursuant to section 38.24 of this Part (rule), including the results of any measurements, analyses and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this subdivision. The information reported shall include data and results as shown in records maintained by the licensee or registrant pursuant to section 38.28 of this Part (rule). Each notification and report shall be in writing and include appropriate identifying data, such as the name of the licensee or registrant, the name of the individual, the individual's social security number, together with the individual's exposure information and, in addition, contain the following statement: "This report is furnished to you under the provisions of Part 38 (12 NYCRR 38) and should be preserved for further reference."

(2) Each licensee or registrant shall advise each worker annually in writing of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee pursuant to section 38.28 of this Part (rule).

(3) At the request of a worker formerly engaged in work controlled by the licensee or the registrant, each licensee or registrant shall furnish to the worker a written report of the worker's exposure to radiation or radioactive material. Such report shall:

(i) be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later;

(ii) cover, within the period of time specified in the request, the cumulative occupational radiation dose received by the individual from exposure to radiation from radiation sources licensed by or registered with, the commissioner;

(iii) contain the results of any calculations and analysis of radioactive material deposited in such individual's body, including any bioassay or other medical evaluation services of which records are required by section 38.28 of this Part (rule); and

(iv) include the dates and locations of work under the license or registration in which the worker participated during this period.

(4) When a licensee or registrant is required pursuant to section 38.29 of this Part (rule) to report to the commissioner any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide to the individual a written report on the exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the commissioner.

(5) At the request of any worker who has been engaged in a work assignment in an area controlled by a licensee or registrant for purposes of radiation protection, and who is terminating employment in such work assignment, the licensee or registrant shall provide a written report of the radiation dose received by that worker from operations of the licensee or registrant during that current year or fraction thereof. The report shall be provided to the worker or the worker's designee at termination, and if the final determined personnel monitoring results are not available at that time, a written estimate of that dose shall be provided in the interim. Estimated doses shall be clearly indicated as such.

(e) Special information. Each person who possesses a radiation source shall, when so ordered by the commissioner upon his finding such services to be necessary or desirable for determining the extent of an individual's occupational exposure to a radiation source, make available to the individual bioassay services or other appropriate medical evaluations and shall furnish to the commissioner copies of the reports of such services.

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed: July 6, 1978; June 9, 1994;  
**Note:** amd. filed April 15, 1999 eff. May 5, 1999. Amended (a).

**§ 38.26 Respiratory protection and controls to restrict internal exposure in restricted areas.**

(a) Use of process or other controls.

(1) The licensee shall use, to the extent practicable, process or other engineering controls such as containment or ventilation to control the concentrations of radioactive material in air.

(2) When it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee or registrant shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

- (i) control of access; or
- (ii) limitation of exposure times; or
- (iii) use of respiratory protection equipment; or
- (iv) other controls.

(b) Use of individual respiratory protection equipment.

(1) If the licensee or registrant uses respiratory protection equipment to limit intakes pursuant to paragraph (a)(2) of this section:

- (i) Except as provided in subparagraph (ii) of this paragraph the licensee or registrant shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health/Mine Safety and Health Administration (NIOSH/MSHA).
- (ii) If the licensee wishes to use equipment that has not been tested or certified by NIOSH/MSHA, has not had certification extended by NIOSH/MSHA, or for which there is no schedule for testing or certification, the licensee or registrant shall submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.
- (iii) The licensee shall implement and maintain a respiratory protection program that includes:

- (a) air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures;
- (b) surveys and bioassays, as appropriate, to evaluate actual intakes;
- (c) testing of respirators for operability immediately prior to each use;
- (d) written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and recordkeeping; and
- (e) determination by a physician prior to initial fitting of respirators, and at least every 12 months thereafter, that the individual user is physically able to use the respiratory protection equipment.

(iv) The licensee or registrant shall issue a written policy statement on respirator usage covering:

- (a) the use of process or other engineering controls, instead of respirators;
- (b) the routine, non-routine, and emergency use of respirators; and
- (c) the length of periods of respirator use and relief from respirator use.

(v) The licensee or registrant shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

(vi) The licensee or registrant shall use equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities, such as adequate skin protection, when needed.

(2) When estimating exposure of individuals to airborne radioactive materials, the licensee or registrant may make allowance for respiratory protection equipment used to limit intakes pursuant to paragraph (a)(2) of this section, provided that the following conditions, in addition to those in paragraph (1) of this subdivision, are satisfied:

- (i) The licensee selects respiratory protection equipment that provides a protection factor greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix A-13, Table I, Column 3, *infra*. However, if the selection of respiratory protection with a protection factor greater than this

multiple is inconsistent with the goal specified in paragraph (a)(2) of this section, of keeping the total effective dose equivalent ALARA, the licensee or registrant may select respiratory protection equipment with a lower protection factor provided that such a selection would result in total effective dose equivalent that is ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used.

(ii) The licensee or registrant shall obtain authorization from the commissioner before assigning respiratory protection factors in excess of those specified in Table 6 of section 38.41 of this Part (rule). The commissioner may authorize a licensee or registrant to use higher protection factors upon receipt of an application that:

(a) describes the situation for which a need exists for higher protection factors; and

(b) demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

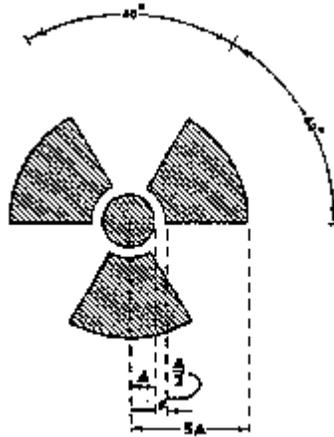
(3) In an emergency, the licensee shall use as emergency equipment only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

(4) The licensee shall notify the commissioner in writing at least 30 days before the date that respiratory protection equipment is first used pursuant to this subdivision.

**Historical Note:** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; renum. 38.22, new filed June 9, 1994 eff. June 29, 1994.

**§ 38.25 Radiation symbol, signs, labels and control devices.**

(a) Standard radiation symbol. Unless otherwise authorized by this Part (rule) or by the commissioner, the symbol prescribed by this section shall use the colors magenta, purple, or black on yellow background. The symbol prescribed is the three-bladed design and shall be as illustrated below:



(1) Cross-hatched area is to be magenta, purple, or black.

(2) The background is to be yellow.

(3) Exception to color requirements for standard radiation symbol. Notwithstanding the requirements of this subdivision, licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation, and which are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

(4) Additional information on signs and labels. In addition to the contents of signs and labels prescribed in this Part, the licensee or registrant shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

(b) (1) Posting requirements.

(i) Posting of radiation areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA".

(ii) Posting of high radiation areas. The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA".

(iii) Posting of very high radiation areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA".

(iv) Posting of airborne radioactivity areas. The licensee or registrant shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA".

(v) Posting of areas or rooms in which licensed or registered material is used or stored. The licensee or registrant shall post each area or room in which there is used or stored an amount of licensed or registered material exceeding 10 times the quantity of such material specified in Table 4 of section 38.41 of this Part (rule) with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)".

(2) Exceptions to posting requirements.

(i) A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than eight hours, if each of the following conditions is met:

(a) the sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this Part (rule); and

(b) the area or room is subject to the licensee's or registrant's control.

(ii) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.

(c) Labeling containers and radiation machines.

(1) The licensee or registrant shall ensure that each container of licensed or registered material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL". The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, sufficient to permit individuals handling or using containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

(2) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

(3) Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

(4) Exceptions to labeling requirements. A licensee or registrant is not required to label:

(i) containers holding licensed material in quantities less than the quantities listed in Table 4 of section 38.41 of this Part (rule);

(ii) containers holding licensed material in concentrations less than those specified in Appendix A-13, Table III of section 38.41 of this Part (rule);

(iii) for laboratory containers, such as beakers, flasks, and test tubes, used transiently in laboratory procedures (i.e. for a period of a few hours) in the presence of an authorized user;

(iv) containers holding licensed material when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation for radioactive material;

(v) containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot-cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

(vi) installed manufacturing or process equipment, such as chemical process equipment, piping, and tanks.

(d) Control of access to high radiation areas.

(1) The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

(i) a control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 1 mSv (0.1 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates;

(ii) a control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area, and the supervisor of the activity, are made aware of the entry; or

(iii) entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

(2) In place of the controls required by paragraph (1) of this subdivision, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(3) The licensee or registrant may use alternative methods for controlling access to high radiation areas if they are approved by the commissioner as effective at accomplishing such control.

(4) The licensee or registrant shall establish the controls required by paragraphs (1) and (3) of this subdivision in a way that does not prevent individuals from leaving a high radiation area.

(5) The licensee or registrant is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation for radioactive material, provided that:

(i) the packages do not remain in the area longer than three days; and

(ii) the dose rate at one meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.

(e) Control of access to very high radiation areas. In addition to the requirements in subdivision (d) of this section, the licensee or registrant shall institute additional measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 5 Gy (500 rad) or more in one hour at one meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to radiation sources subject to subdivision (f) of this section.

(f) Control of access to very high radiation areas-irradiators.

(1) This subdivision applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. This subdivision does not apply to sources of radiation that are used in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create a radiation level of 5 Gy (500 rad) or more in one hour at one meter in an area that is accessible to any individual.

(2) Each area in which there may exist radiation levels in excess of 5 Gy (500 rad) in one hour at one meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

(i) Each entrance or access point shall be equipped with entry control devices which:

(a) function automatically to prevent any individual from inadvertently entering a very high radiation area;

(b) permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in one hour; and

(c) when actuated, prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of 1 mSv (0.1 rem) in one hour.

(ii) Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by subparagraph (i) of this paragraph:

(a) the radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in one hour; and

(b) conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard as well as at least one other authorized individual, who is physically present, familiar with the activity and prepared to render or summon assistance, aware of the failure of the entry control devices.

(iii) The licensee or registrant shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:

(a) the radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in one hour; and

(b) conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard; as well as to make the licensee or registrant or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

(iv) When the shield for stored sealed sources is a liquid, the licensee or registrant shall provide means to monitor the integrity of the shield and to signal, automatically, loss of shielding to a level at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in one hour.

(v) Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of subparagraphs (iii) and (iv) of this paragraph.

(vi) Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation, and in time for any individual in the area to operate a clearly identified control device which must be installed in the area, and which will prevent the source of radiation from being put into operation.

(vii) Each area shall be controlled by use of such procedures and devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

(viii) Prior to the first individual's entry into each very high radiation area after any use of the source of radiation, the area shall be checked by a radiation measurement. The area may not be used unless the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in one hour.

(ix) The entry control devices required in subparagraph (i) of this paragraph shall have been tested for proper functioning as follows:

(a) testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day;

(b) testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

(c) the licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

(x) The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

(xi) Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such procedures and devices as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and to automatically prevent loose radioactive material from being carried out of the area.

(3) Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of this subdivision which will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of paragraph (2) of this subdivision, such as those for the automatic control of radiation levels, may apply to the commissioner for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in paragraph (2) of this subdivision. At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation present that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

(4) The entry control devices required by paragraphs (2) and (3) of this subdivision shall be established in such a way that no individual will be prevented from leaving the area.

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed: July 6, 1978; June 9, 1994 eff.  
**Note:** June 29, 1994.

**§ 38.24 Personnel monitoring.**

(a) External radiation sources.

(1) Each person who possesses any radiation source shall supply and require the proper use of appropriate, calibrated and operable individual monitoring devices by:

(i) adults likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in section 38.18(a)(1) of this Part (rule);

(ii) minors and declared pregnant women likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in section 38.18 (g) or (h) of this Part (rule); and

(iii) individuals entering a high or very high radiation area.

(2) A person supplying personnel monitoring devices to individuals as required by this subdivision shall ensure that the individuals wear such devices as follows:

(i) An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure.

(ii) An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman, pursuant to section 38.18(h)(1) of this Part (rule), shall be located at the waist under any protective apron worn by the woman.

(iii) An individual monitoring device used for monitoring the eye dose equivalent shall be located at the neck outside any protective apron worn by the individual, or at an unshielded location closer to the eye.

(iv) An individual monitoring device used for monitoring the dose to the extremities shall be worn on the extremity likely to receive the highest exposure. The device shall be oriented to measure the highest dose to the extremity being monitored.

(3) All personnel monitoring devices, except for direct and indirect reading dosimeters and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and which are supplied pursuant to this subdivision or to conditions specified in a license or registration, shall be processed and evaluated by a dosimetry processor:

(i) holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(ii) approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximate the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

(b) Intake of radioactive material. Each licensee shall perform all appropriate measurements of those specified in section 38.18(d)(1) of this Part (rule) which will enable him/her to determine the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(1) adults likely to receive, in one year, an intake in excess of 10 percent of the applicable ALI in Appendix A-13, Table I, columns 1 and 2, *infra*; and

(1) minors and declared pregnant women likely to receive, in one year, a committed effective dose equivalent in excess of 0.50 mSv (0.05 rem).

**Historical Note:** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; renum. 38.21, new filed June 9, 1994 eff. June 29, 1994.

**§ 38.23 Vacating installations and property.**

(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 (rule). A survey shall be made after such decontamination and submitted to the commissioner. No such installation or premises shall be vacated, sold or transferred until the decontamination survey has been accepted by the commissioner as demonstrating that the residual radioactive contamination of the installation and premises is as low as is 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 (rule). A survey shall be made after such decontamination and submitted to the commissioner. No such property shall be assigned, sold, leased or transferred until such survey has been accepted by the commissioner as demonstrating that the residual radioactive contamination of the property is as low as is reasonably achievable.

(c) Plans for completion of decommissioning.

(1) In addition to the requirements of subdivisions (a) and (b) of this section, the licensee shall submit a plan for completion of decommissioning if the procedures necessary to carry out decommissioning have not been previously approved by the commissioner and could increase potential health and safety impacts to workers or to the public such as in any of the following cases:

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

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

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

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

(2) Procedures with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(3) The proposed decommissioning plan, if required by paragraph (1) of this subdivision or by license condition, must include:

(i) a description of planned decommissioning activities;

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

(iii) a description of the planned final radiation survey; and

(iv) an updated detailed cost estimate for decommissioning, a comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(4) The proposed decommissioning plan will be approved by the commissioner if the information therein demonstrates that the decommissioning will be completed as soon as is reasonable and that the health and safety of workers and the public will be adequately protected.

(5) Upon approval of the decommissioning plan by the commissioner, the licensee shall complete decommissioning in accordance with the approved plan. As a final step in decommissioning, the licensee shall again submit the information required in subdivision

(a) of this section and shall certify the disposition of accumulated wastes from decommissioning.

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; amd. filed June 25, 1985; repealed, new filed June 9, 1994; amd. filed April 15, 1999 eff. May 5, 1999. Amended (a) – (b).

## **§ 38.22 Surveys, checks and tests.**

(a) Surveys-general. Each person who possesses any radiation source shall make, or cause to be made, the applicable surveys required under this section and such additional surveys as may be necessary for such person to comply with other provisions of this Part (rule).

(b) Instrumentation. Each person required to perform a survey by this Part (rule) shall be provided with or have available appropriate calibrated and operable instruments capable of detecting and measuring radiation.

(c) Radiation equipment-surveys. Every installation and mobile source wherein radiation equipment is to be used shall be surveyed during the initial operation of such equipment and whenever any change is made in such installation or mobile source or in its use that might increase the radiation level to which an individual could be exposed. When vibrations or other physical conditions exist in such installations or mobile sources which may cause changes in the protective features, surveys shall be made at least every six months.

(d) Radioactive materials-surveys. Any installation wherein radioactive materials are handled or installed which has any readily accessible area in which there is reasonable expectation that a radiation level will exist in excess of 2 millirems per hour, or any mobile source which could create such a radiation level, shall be surveyed during the initial operation and whenever any change is made in such installation or mobile source or in its use that might increase the radiation level to which an individual could be exposed.

(e) Unsealed sources-surveys. Radiation installations wherein radioactive material not contained in a sealed source is handled or installed shall be surveyed at least once a month for radioactive contamination. With regard to radioactive contamination of surfaces, compliance with section 38.17(a) of this Part (rule) may be assumed if the limits specified in Table 5 of section 38.41 of this Part (rule) are met.

(f) Sealed sources-leak test.

(1) Each sealed source containing radioactive material other than hydrogen 3, with a half life greater than 30 days and in any form other than gas, shall be tested for leakage prior to initial use and at successive intervals thereafter not exceeding six months, except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not exceeding three months. Notwithstanding the periodic leak test required by this paragraph, any licensed sealed source is exempt from such leak tests when the source contains 3.7 MBq (100 microcuries) or less of beta and/or gamma emitting material or 370 kBq (10 microcuries) or less of alpha emitting material. Except for alpha sources, the periodic leak test required by this paragraph shall not apply to sealed sources that are stored and not being used. The sources excepted from this requirement shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer. In the absence of the delivery of a certificate by the transferor to the transferee indicating that a test pursuant to the applicable provisions of this Part (rule) was made within six months prior to the transfer, the source shall not be used

until tested for leakage. If there is reason to suspect that a sealed source might have been damaged, or might be leaking, such source shall be tested for leakage before further use.

(2) The test sample shall be taken from selected accessible surfaces of the sealed source or from surfaces of the device in which the source is permanently mounted or stored. The selected surfaces should be those on which contamination would be expected to accumulate if the source was leaking. Where applicable, the test sample shall be taken with the source in the "off" position.

(3) The leak test technique shall be capable of detecting 185 Bq (0.005 microcurie) of removable radioactivity, or from sealed radium sources, the escape of radon at the rate of 37 Bq (0.001 microcuries) per 24 hours.

(4) Detection of a leak in any sealed source in excess of the sensitivity levels set forth in this subdivision shall result in immediate suspension of the use of such source until it is decontaminated and repaired or disposed of in accordance with section 38.20 of this Part (rule).

(5) Records of leak test results shall be kept in units of microcuries per test sample and maintained for inspection by the commissioner. A report shall be submitted to the commissioner for each source found to be leaking in excess of the above sensitivity levels within five days of detection of the leak and shall describe the equipment involved, the test results, and the corrective actions taken.

(g) Protective devices. All protective devices such as interlocks, safety switches, fume hoods, filters and trapping devices for radioactive gases, shall be maintained in good repair and proper operating condition.

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; repealed, new  
**Note:** added by renum. and amd. 38.26, filed June 9, 1994 eff. June 29, 1994.

**§ 38.21 Limitations on human use.**

No person shall use any radiation source for human use, except when such use and person are licensed or authorized by the State Department of Health or the New York City Department of Health.

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; amd. filed  
**Note:** June 25, 1985; repealed, new added by renum. 38.24, filed June 9, 1994  
eff. June 29, 1994.

**§ 38.20 Disposal of radioactive material.**

(a) No person shall dispose of any radioactive material except by transfer to an authorized recipient or by one of the following methods:

(1) by decay in storage in accordance with a license condition authorizing this practice; or

(2) by release in effluents in accordance with the regulations of the New York State Department of Environmental Conservation in 6 NYCRR Part 380.

(b) [Reserved]

(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<sup>1</sup>.

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed: July 6, 1978; June 9, 1994;  
**Note:** amd. filed April 15, 1999 eff. May 5, 1999. Added (c) (d)

**§ 38.19 Radiation dose limits for individual members of the public.**

(a) Dose limits for individual members of the public.

(1) Each licensee or registrant shall conduct operations so that:

(i) the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour; and

(ii) the total effective dose equivalent to individual members of the public from the licensed or registered operation, exclusive of the dose contribution from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with section 38.20 of this Part (rule), does not exceed 1 mSv (0.1 rem) in a year.

(2) If radioactive materials are released into the air or water by any person in such a manner that the radioactive materials may be reconcentrated in an unrestricted area or may be added to any other radioactive materials released to an unrestricted area, the commissioner may further restrict the release by such person to assure that the limits set forth in this Part (rule) are not exceeded.

(b) Compliance with dose limits for individual members of the public.

(1) The licensee or registrant shall make or cause to be made, surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas, and shall use the results to evaluate and ensure compliance with the dose limits for individual members of the public in subdivision (a) of this section.

(2) The licensee or registrant shall demonstrate compliance with paragraph (1) of this subdivision by showing by measurement or calculation that:

(i) the total effective dose equivalent to the individual likely to receive the highest dose does not exceed the annual dose limit; or

(ii) the annual average concentrations of radioactive material released at the boundary of the restricted area do not exceed the values specified in Appendix A-13, Table II; and, if an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in a year.

(1) A licensee or registrant shall maintain records of measurements and calculations used to demonstrate compliance with the annual dose limit in subdivision (a) of this section.

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; renum. 38.16, new  
**Note:** filed June 9, 1994 eff. June 29, 1994.

**§ 38.18 Occupational dose limits.**

(a) Occupational dose limits for adults.

(1) Except for planned special exposures pursuant to subdivision (f) of this section, no person shall transfer, receive, possess or use any radiation source so as to cause any individual adult to receive an occupational dose from all sources of radiation that exceeds any of the following limits:

(i) an annual limit, which is the more limiting of:

(a) a total effective dose equivalent equal to 0.05 Sv (5 rem); or

(b) the sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue, other than the lens of the eye, equal to 0.50 Sv (50 rem);

(ii) annual limits to the lens of the eye, to the skin, and to the extremities which are:

(a) an eye dose equivalent of 0.15 Sv (15 rem); and

(b) a shallow dose equivalent of 0.50 Sv (50 rem) to the skin or to any extremity.

(2) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures must be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. (See paragraph [f][5] of this section.)

(3) The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure. If an individual's monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable, the deep dose equivalent, eye dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits.

(4) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Appendix A-13 of section 38.41 of this Part (rule), and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits.

(5) Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week. (See footnote 3 of Appendix A-13 of section 38.41 of this Part [rule].)

(6) The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. (See subdivision [e] of this section.)

(b) Compliance with requirements for summation of external and internal dose.

(1) Requirements for summation of external and internal doses. If the licensee or registrant is required to monitor pursuant to both subdivisions (a) and (b) of section 38.24 of this Part (rule), the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to subdivision 38.24 (a) or only pursuant to subdivision 38.24(b) of this Part (rule), then summation is not required in order to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses by meeting one of the conditions specified in paragraph (2) of this subdivision, and the conditions in paragraphs (3) and (4) of this subdivision. The dose equivalents for the lens of the eye, the skin, and the extremities are not to be included in the summation, but are subject to separate limits.

(2) Intake by inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

(i) the sum of the fractions of the inhalation ALI for each radionuclide; or

(ii) the total number of derived air concentrations-hours (DAC-hours) for all radionuclides divided by 2,000; or

(iii) the sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors,  $W_T$ , and the committed dose equivalent,  $H_{T,50}$ , per unit intake is greater than 10 percent of the maximum weighted value of  $H_{50}$ , that is,  $W_T H_{T,50}$  per unit intake for any organ or tissue.

(3) Intake by oral ingestion. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee or registrant shall account for this intake and include it in demonstrating compliance with the limits.

(4) Intake through wounds or absorption through skin. The licensee or registrant shall evaluate and account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for pursuant to this paragraph.

(c) Determination of external dose from airborne radioactive material.

(1) Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, eye dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud (see footnotes 1 and 2 of Appendix A-13 of section 38.41 of this Part [rule]).

(2) Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual in these cases shall be based upon measurements using instruments or individual monitoring devices.

(d) Determination of internal exposure.

(1) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required under section 38.24 of this Part (rule), take any of the following measurements as may be necessary for timely and appropriate detection and assessment of intake of radioactivity by individuals:

(i) concentrations of radioactive materials in air in work areas;

(ii) quantities of radionuclides in the body;

(iii) quantities of radionuclides excreted from the body; or

(iv) combinations of these measurements.

(2) Unless respiratory protective equipment is used, as provided in section 38.26 of this Part (rule), or the assessment of intake is based on bioassays, the licensee or registrant shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

(3) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee or registrant may:

(i) use that information to calculate the committed effective dose equivalent, and, if used, the licensee or registrant shall document that information in the individual's record; and

(ii) separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent.

(4) If the licensee chooses to assess intakes of Class Y material using the measurements listed in subparagraph (1)(ii) or (iii) of this subdivision, the licensee or registrant may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by section 38.29(b)(1) and (2) of this Part (rule). This delay permits the licensee or registrant to make additional measurements basic to the assessments.

(5) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

(i) the sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix A-13, for each radionuclide in the mixture; or

(ii) the ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

(6) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

(7) When a mixture of radionuclides in air exists, a licensee may disregard certain radionuclides in the mixture if:

(i) the licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in subdivision (a) of this section and in complying with the monitoring requirements in section 38.24(b) of this Part (rule);

(ii) the concentration of any radionuclide disregarded is less than 10 percent of its DAC; and

(iii) the sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

(8) When determining the committed effective dose equivalent, the following information may be considered:

(i) in order to calculate the committed effective dose equivalent, the licensee or registrant may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 0.05 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent;

(ii) for an ALI and associated DAC which are based upon the nonstochastic organ dose limit of 0.50 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in Appendix A-13. The licensee or registrant may, as a

simplifying assumption, use the stochastic ALIs to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALIs, the licensee or registrant shall also demonstrate that the limit in clause (a)(1)(i)(b) of this section is met.

(e) Determination of prior occupational dose.

(1) For each individual who may enter the licensee's or registrant's restricted area and is likely to receive, in a year, an occupational dose requiring monitoring pursuant to section 38.24 of this Part (rule), the licensee or registrant shall:

- (i) determine the occupational radiation dose received during the current year; and
- (ii) request in writing the records of lifetime cumulative occupational radiation dose.

(2) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

- (i) the internal and external doses received by the individual from all previous planned special exposures; and
- (ii) all doses in excess of the limits received during the individual's lifetime, including doses received during accidents and emergencies.

(3) In complying with the requirements of paragraph (1) of this subdivision, a licensee or registrant may:

- (i) accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year;
- (ii) accept, as the record of lifetime cumulative radiation dose, a completed and up-to-date department form for cumulative occupational radiation exposure history, or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and
- (iii) obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(4) The licensee or registrant shall record the exposure history, required by paragraph (1) of this subdivision, on the department form for cumulative occupational radiation exposure history, or other clear and legible record and shall include all the information required on that form.

(i) The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing the form or record. For any period for which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on the form or record indicating the periods of time for which data are not available.

(ii) Licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents, or intakes of radionuclides, which were assessed under the regulations in effect before the effective date of these regulations. Occupational exposure histories obtained and recorded on the department form for cumulative occupational radiation exposure history before the effective date of these regulations would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

(5) If the licensee or registrant is unable to obtain complete records of an individual's current and previously accumulated occupational dose, the licensee or registrant shall:

(i) when establishing administrative controls under paragraph (a)(6) of this section for the current year, assume that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

(ii) not authorize the individual to receive any planned special exposures.

(6) The licensee or registrant shall retain the records on the department form for cumulative occupational radiation exposure history or equivalent, until the commissioner terminates each pertinent license or registration. The licensee or registrant shall retain records used in preparing this form or equivalent for three years after the record is made.

(f) Planned special exposures. A licensee or registrant may authorize an adult worker to receive doses which are in addition to, and which are accounted for separately from, the doses received under the limits specified in subdivision (a) of this section provided that each of the following conditions is satisfied:

(1) The licensee or registrant authorizes the planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure are unavailable or impractical.

(2) The licensee or registrant, and the employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

(3) Before a planned special exposure, the licensee or registrant ensures that each worker involved is:

(i) informed of the purpose of the planned operation;

(ii) informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

(iii) instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

(4) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by paragraph (2) of subdivision (e) of this section.

(5) Subject to paragraph (2) of subdivision (a) of this section, the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures that would exceed:

(i) the numerical values of any of the dose limits in paragraph (1) of subdivision (a) of this section in any year; and

(ii) five times the annual dose limits in paragraph (1) of subdivision (a) of this section during the individual's lifetime.

(6) The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with section 38.28(e) of this Part and submits a written report in accordance with section 38.29(d).

(7) The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to paragraph (1) of subdivision (a) of this section but shall be included in evaluations required by paragraphs (4) and (5) of this subdivision.

(g) Occupational dose limits for minors. The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in subdivision (a) of this section.

(h) Dose to an embryo/fetus.

(1) The licensee or registrant shall ensure that the dose to an embryo/fetus during the entire pregnancy, which results from occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem). (See section 38.28[f] for recordkeeping requirements.)

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

(3) The dose to an embryo/fetus shall be taken as the sum of:

(i) the deep dose equivalent to the declared pregnant woman during the entire pregnancy period; and

(ii) the dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman during the entire pregnancy period.

(4) If by the time the woman declares pregnancy to the licensee or registrant, the dose to the embryo/fetus exceeded 4.5 mSv (0.45 rem), the licensee or registrant shall be deemed to be in compliance with paragraph (1) of this subdivision if the additional dose to the embryo/fetus does not exceed 0.50 mSv (0.05 rem) during the remainder of the pregnancy.

**Historical:** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; renum. 38.15, new  
**Note** filed June 9, 1994; amd. filed April 15, 1999 eff. May 5, 1999. Amended (h) (2).

**§ 38.17 Responsibility for radiation safety and radiation protection programs.**

No person shall operate a radiation installation unless that person:

- (a) makes every effort to maintain radiation exposures and releases of radioactive material as low as reasonably achievable (ALARA); and
- (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 the Part (rule) and the installation operator shall provide a radiation safety officer as described in section 38.3 (a) (79) of this Part (rule). The radiation safety officer shall be delegated authority to ensure the implementation of this radiation protection program and shall be responsible for its day-to-day conduct;
- (c) conducts, or causes to be conducted, an annual review of the radiation protection program content and implementation, and of the performance of the radiation safety officer; and
- (d) implements the ALARA requirements of subsection (a) of this section, and notwithstanding the requirements of subsection 38.19(a) (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 license 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.

**Historical Note:** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; renum. 38.14, new filed June 9, 1994; amd. filed April 15, 1999 eff. May 5, 1999. Amended (b), added (d).

**§ 38.16 Licensees and contractors of the United States Nuclear Regulatory Commission and United States NRC-designated contractors doing work for other United States government agencies.**

(a) Activities licensed by the United States Nuclear Regulatory Commission within the State. Each person who holds a license from the United States Nuclear Regulatory Commission authorizing activities within the State shall be exempt from the requirements of this Part (rule) with respect to such activities during the period that such license is valid; provided, however, that such person:

(1) shall afford the commissioner access to all records which such person is required to maintain pursuant to the United States Nuclear Regulatory Commission's rules and regulations or pursuant to the provisions of the United States Nuclear Regulatory Commission licenses;

(2) shall afford the commissioner opportunity to sample effluents, and to conduct such measurement or survey of levels of radiation and radioactive contamination as will not substantially interfere with or interrupt any activities licensed by the United States Nuclear Regulatory Commission; and

(3) shall afford the commissioner access to the facilities of such person in order to accomplish the foregoing review of records, sampling of effluents and conduct of measurements or surveys.

(b) Contractors of the United States Nuclear Regulatory Commission and United States NRC-designated contractors doing work for other United States government agencies. Any United States Nuclear Regulatory Commission contractor or subcontractor and any United States NRC-designated contractor or subcontractor of the following categories operating within this State is exempt from the requirements of this Part (rule) to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers, owns or acquires sources of radiation:

(1) United States Nuclear Regulatory Commission-designated prime contractors performing work for other United States government agencies at United States government-owned or controlled sites;

(2) United States Nuclear Regulatory Commission-designated prime contractors of other United States government agencies and performing research in, or development, manufacture, storage, testing or transportation of atomic weapons or components thereof;

(3) United States Nuclear Regulatory Commission-designated prime contractors of other United States government agencies using or operating nuclear reactors or other nuclear devices in a United States government-owned vehicle or vessel; and

(4) any other prime contractor or subcontractor of the United States Nuclear Regulatory Commission or United States Nuclear Regulatory Commission-designated prime contractor or subcontractor doing work for other United States government agencies when the State and the United States Nuclear Regulatory Commission jointly determine that under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety and that the exemption of such contractor or subcontractor is otherwise appropriate.

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; renum. 38.13,  
**Note:** new added by renum. 38.19, filed June 9, 1994 eff. June 29, 1994

**§ 38.15 Holders of licenses or permits.**

(a) The holder of a license or permit issued by the State Department of Health, the New York City Department of Health, the United States Nuclear Regulatory Commission, and any agreement state, or any licensing nonagreement state, may bring, possess or use radioactive material covered by such license or permit within the commissioner's jurisdiction for a period not in excess of 30 days in any calendar year without obtaining a license from the commissioner, provided that:

- (1) such license or permit does not limit the holder's possession or use of such material to a specific installation or installations;
- (2) such holder, at least seven days prior to engaging in such activities within the commissioner's jurisdiction, files with the commissioner a notice indicating the period, type and location of proposed possession and use within the commissioner's jurisdiction and a copy of the license or permit. At the discretion of the commissioner, oral notification of the commissioner or notification of the commissioner less than seven days prior to engaging in such activities may be accepted in lieu of the filing requirement under this paragraph;
- (3) such holder supplies such additional information as the commissioner may reasonably request;
- (4) such holder, during the period of his possession and use of such material within the commissioner's jurisdiction, complies with all relevant provisions of this Part (rule), and any additional requirements which the commissioner may impose and which are reasonable under the circumstances;
- (5) such holder, during such period, complies with all terms and conditions of his license or permit, except such terms or conditions as may be inconsistent with this Part (rule).

(b) Any holder of a license or permit issued by the State Department of Health, the New York City Department of Health, the United States Nuclear Regulatory Commission, any agreement state, or any licensing nonagreement state which authorizes the holder to manufacture, install or service a device of the type which is generally licensed and specified in Table 3, item (b) of this Part (rule), may install or service such device without obtaining a license from the commissioner, provided that:

- (1) such person shall file a report with the commissioner within 30 days after the end of each calendar quarter in which any device is transferred to or installed within the commissioner's jurisdiction. Such report shall contain the name and address of each person receiving such a device, shall identify the type of device or devices so transferred, and shall state the quantity and type of radioactive material contained in such device or devices;

(2) any such device is installed and serviced in accordance with the terms of the license or permit issued to such person;

(3) such person shall assure that any labels required to be affixed to any such device shall bear a statement that reads "Removal of this label is prohibited"; and

(4) the person to whom such holder transfers any such device or on whose premises such holder installs or services any such device has a copy of the general license requirements or equivalent requirements outlined in Table 3, item (b) of this Part (rule).

**Historical Note:** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; repealed, new added by renum. 38.18, filed June 9, 1994 eff. June 29, 1994.

**§ 38.14 Procedural provisions.**

(a) Review of actions on applications, licenses, security and approvals. Any order issued by the commissioner under this Part (rule) shall constitute an order for the enforcement of this Part (rule) under section 21 of the Labor Law and accordingly an order made under the provisions of the Labor Law within the meaning of section 101 thereof.

(b) Hearings. Except when immediate action is required to secure safety, a license shall not be revoked, suspended or restrictively amended by the commissioner without the consent of the licensee unless the licensee has been given reasonable notice and an opportunity to be heard.

**Historical Note:** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; repealed, new added by renum. 38.17, filed June 9, 1994 eff. June 29, 1994.

**§ 38.13 Removal of radioactive material.**

(a) Notwithstanding any exemptions contained in this Part (rule), any person who uses, possesses or stores radioactive materials in violation of any provision of law or of this Part (rule) or of his own license, or of any order of the commissioner, shall, upon order of the commissioner, remove or provide for the removal of such materials at his own expense through the use of an authorized transferee and shall decontaminate the installation to the limits specified in Table 5 of this Part (rule).

(b) In the event that a person fails to comply with the provisions of subdivision (a) of this section, the commissioner may seize and remove the radioactive material and, if necessary, decontaminate the installation to the limits specified in Table 5 of this Part (rule), and shall be reimbursed for the expense thereof by the person failing to comply with the provisions of subdivision (a) of this section. If such person is a corporation, the officers and agents who knowingly permit the corporation to violate the provisions of subdivision (a) of this section shall be personally responsible for such expense.

**Historical Note** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; repealed, new added by renum. 38.16, filed June 9, 1994 eff. June 29, 1994

## **§ 38.12 Conditions of specific licenses.**

(a) It is hereby made a condition of each specific license:

(1) that the licensee shall confine his possession and use of licensed radioactive material to such location or locations and for such purpose or purposes as the license may authorize; provided, however, that except as otherwise provided in such license or this Part, such license shall be deemed to authorize the licensee to transfer the material covered by such license to any other person authorized to receive it by the commissioner, the State Department of Health, the New York City Department of Health, the United States Nuclear Regulatory Commission or any agreement state;

(2) that the licensee shall notify the commissioner by letter within 30 days if an authorized user or radiation safety officer permanently discontinues performance of duties under the license;

(3) that any license covering the use of special nuclear material in the course of which licensed use additional special nuclear material is produced, shall be deemed to cover any such special nuclear material so produced; provided, however, that the total quantity of special nuclear material possessed by the licensee is not sufficient to form a critical mass;

(4) each person who possesses any radiation source shall secure such source against its unauthorized removal from its place of storage or use. The following additional restrictions apply to noncontrolled areas:

(i) radiation sources stored in a noncontrolled area shall be stored in a locked facility in the original shipping container, or a container providing equivalent radiation protection. Such a facility may be a cabinet, a safe or a room, provided that the facility is locked at all times when no activities are in progress relating to the use of the radiation sources;

(ii) radiation sources in a noncontrolled area and not in storage shall be tended under the constant surveillance and immediate control of the licensee or registrant.

(b) The commissioner may at any time set forth in any license or incorporate by reference therein, additional conditions, restrictions or requirements applicable to the licensee's transfer, receipt, possession or use of the radioactive material covered by such license in order to protect health and safety and to minimize danger to life and property from radiation hazards.

(c) Licensees required to submit emergency plans by section 38.6(d) of this Part (rule) shall follow the emergency plan approved by the commissioner. The licensee may change the approved plan without the approval of the commissioner only if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the

commissioner and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the commissioner

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed: July 6, 1978; June 9, 1994 eff.  
**Note:** June 29, 1994

**§ 38.11 Amendment, suspension or revocation of licenses.**

Specific and general licenses shall be subject to amendment, suspension or revocation by reason of amendment of the commissioner's regulations, enactment or amendment of any other applicable law, or amendment or promulgation of any other applicable rule, regulation, or order. The commissioner may amend, revoke or suspend any license in whole or in part, for:

- (a) any material misstatement in the application therefor or in any supplementary statement thereto;
- (b) any condition revealed by such application, supplementary statement, report, record, inspection or other means, which would warrant the commissioner to refuse to grant a license on an original application; or
- (c) any violation or failure to observe any of the applicable terms or provisions of such license, this Part (rule), or any other applicable rule, regulation, code or order now or hereafter in effect.

**Historical Note:** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; amd. filed June 25, 1985; renum. 38.9, new filed June 9, 1994 eff. June 29, 1994.

**§ 38.10 Renewal or amendment of specific licenses.**

Any application by a licensee for the renewal or amendment of a license shall be considered as an application for a license and shall be filed in accordance with section 38.6 of this Part (rule); and any such application for amendment shall set forth the reasons for such requested amendment. In considering any such application for renewal or amendment, the commissioner will apply the requirements set forth in section 38.8 of this Part (rule) as appropriate. Corrective amendments of a license may be issued by the commissioner at any time upon his/her initiative.

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed: July 6, 1978; June 9, 1994 eff.

**Note:** June 29, 1994.

### **§ 38.9 Duration of licenses.**

(a) Except as 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 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 (rule). To terminate a license, the licensee must notify the commissioner, transfer all radioactive materials to authorized recipient(s) and comply with the provisions of section 38.23 of this Part (rule).

(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 alternative expiration date is stated in the determination, or is otherwise provided for in the commissioner's Order.

(c) Each specific license continues in effort, beyond the expiration date if necessary, with respect to possession of radioactive material until the commissioner notified 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 months 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) of this section 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 (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.

**Historical Note:** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; repealed, new added by renum. 38.11, filed June 9, 1994; amd. filed April 15, 1999 eff. May 5, 1999.

## § 38.8 General requirements for issuing specific licenses.

### Historical Note

(a) The commissioner will approve an application for, and issue in response thereto, a specific license to transfer, receive, possess and use any radioactive material, if the commissioner determines that the following requirements have been met:

(a) the applicant's proposed use, equipment, facilities and procedures will protect public health and safety, and will minimize danger to life and property, from radiation hazards;

(b) the applicant's radiation detection and measuring instrumentation is appropriate for the uses of radioactive materials requested in the application;

(c) the applicant, (or the applicant's personnel if the applicant is not an individual), is qualified by training and experience to use such radioactive material for each purpose covered by the application so as to protect public health and safety and to minimize danger to life and property from radiation hazards; and

(d) the applicant submits sufficient information to support a determination that the requirements of this section are satisfied.

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed: July 6, 1978; June 9, 1994 eff.  
**Note:** June 29, 1994.

**§ 38.7 Financial assurance for decommissioning.**

(a) Each applicant for a license, renewal thereof or amendment thereto, authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities exceeding 100,000 times the applicable quantities set forth in Table 4 of this Part (rule) shall submit a decommissioning funding plan as described in subdivision (d) of this section. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if  $R$  divided by 100,000 is greater than 1 (unity rule), where  $R$  is defined here as the sum of the ratios of the quantity of each isotope to the applicable value set forth in Table 4 of this Part (rule).

(b) Each applicant for a license, renewal thereof or amendment thereto, authorizing the possession and use of radioactive material of half-life greater than 120 days and in quantities specified in subdivision (c) of this section shall either:

(1) submit a decommissioning funding plan as described in subdivision (d) of this section; or

(2) submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by subdivision (c) of this section using one of the methods described in subdivision (e) of this section. In the case of an applicant for a license, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of subdivision (e) of this section is to be submitted to the commissioner.

(c) Table of required amounts of financial assurance for decommissioning by quantity of material.

(1) Greater than 10,000 but less than or equal to 100,000 times the applicable quantities set forth in Table 4 of this Part (rule) in unsealed form (for a combination of isotopes, if  $R$ , as defined in subdivision (a) of this section, divided by 10,000, is greater than 1, but  $R$  divided by 100,000 is less than or equal to 1): \$750,000.

(2) Greater than 1,000 but less than or equal to 10,000 times the applicable quantities set forth in Table 4 of this Part (rule) in unsealed form (for a combination of isotopes, if  $R$ , as defined in subdivision (a) of this section, divided by 1,000, is greater than 1 but  $R$  divided by 10,000 is less than or equal to 1): \$150,000.

(3) Greater than 10,000,000,000 times the applicable quantities set forth in Table 4 of this Part (rule) in sealed sources or plated foils (for a combination of isotopes, if  $R$ , as defined in subdivision (a) of this section, divided by 10,000,000,000, is greater than 1): \$75,000.

(d) Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from subdivision (e) of this section, including means of adjusting cost estimates and associated funding levels periodically over the life of the installation.

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

(1) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(2) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid should the licensee default. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix C of this Part (rule). A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

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

(ii) The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the commissioner.

(ii) The surety method or insurance must remain in effect until the commissioner has terminated the license.

(3) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time

termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in paragraph (e) (2) of this section.

(4) In the case of State or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in subdivision (c) of this section, and indicating that funds for decommissioning will be obtained when necessary.

(f) Each person licensed under this Part (rule) shall keep records of information important to the safe and effective decommissioning of the installation, as specified in section 38.28 of this Part (rule), in an identified location until the license is terminated by the commissioner. If records of relevant information are kept for other purposes, reference to these records and their locations may be used.

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; amd. filed  
**Note:** June 25, 1985; repealed, new filed March 15, 1993; amd. Filed June 9, 1994 eff  
June 29, 1994. Amended (f).

**§ 38.6 Applications for specific license.**

- a) An application for a specific license shall be made to the commissioner on a form prescribed by him. Such application shall set forth such pertinent information as the commissioner may require. Supplementary statements shall be filed upon the commissioner's request.
- (b) Each application or supplementary statement shall be signed by either the applicant personally or a person duly authorized by the applicant to sign for and on the applicant's behalf.
- (c) As provided by section 38.7 of this Part, certain applications for specific licenses filed under this Part (rule) must contain a proposed decommissioning funding plan or a certification that financial assurance for decommissioning has been provided.
- (d) Emergency plans for responding to a release of radioactive material.
- (1) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in Table 7 of section 38.41 of this Part (rule) "Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," must contain either:
- (i) an evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid; or
  - (ii) an emergency plan for responding to a release of radioactive material.
- (2) One or more of the following factors may be used to support an evaluation submitted under subparagraph (1)(i) of this subdivision:
- (i) the radioactive material is physically separated so that only a portion could be involved in an accident;
  - (ii) all or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;
  - (iii) the release fraction in the respirable size range would be lower than the release fraction shown in Table 7 of section 38.41 of this Part (rule) due to the chemical or physical form of the material;
  - (iv) the solubility of the radioactive material would reduce the dose received;
  - (v) facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Table 7 of section 38.41 of this Part (rule);

(vi) operating restrictions or procedures would prevent a release fraction as large as that shown in Table 7 of section 38.41 of this Part (rule); or

(vii) other factors appropriate for the specific facility.

(3) An emergency plan for responding to a release of radioactive material submitted under subparagraph (1)(ii) of this subdivision must include the following information:

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

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

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

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

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

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

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

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

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

(x) Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide to workers on how to respond to an emergency; including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

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

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

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

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the commissioner. The licensee shall provide any comments received within 60 days to the commissioner with the emergency plan.

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed: July 6, 1978; June 9, 1994 eff.  
**Note:** June 29, 1994.

### § 38.5 Licensing-general requirements.

(a) Overall licensing requirement for radioactive material. Except for radioactive material specified in Table 1 of section 38.41 of this Part (rule), and the removal of source material from its place of deposit in nature, or as otherwise provided by this Part (rule), no person shall transfer, distribute, manufacture, receive, possess or use any radioactive material except pursuant to a specific or general license issued under this Part (rule).

(b) General licenses. Subject to the terms and conditions specified in Table 3 of section 38.41 of this Part (rule), a general license is effective without the filing of an application for a specific license and without the issuance of a specific licensing document by the commissioner.

(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 (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.

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed: July 6, 1978; June 9, 1994;  
**Note:** amd. filed April 15, 1999 eff. May 5, 1999. Added (c).

#### **§ 38.4 Registration and approvals.**

(a) 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 (rule) shall be registered with the commissioner on a form prescribed by him or 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 (rule).

Registration shall be made prior to receipt of the radiation equipment or upon receipt of the generally licensed device. Registration is not complete until it is verified and accepted by the commissioner. If a registered installation is so changed as to render its registration inaccurate, notice thereof shall be given to the commissioner within 48 hours of such change.

(b) Every distributor or retailer of radiation equipment, or agent thereof, or radiation consultant, who installs, tests or otherwise services radiation equipment shall be registered with the Commissioner on a form prescribed by him. Registration shall be made prior to undertaking such installation, testing for servicing. Such distributors, retailers, agents or consultants shall, while engaged in installation, testing or other servicing of radiation equipment, comply with the requirements of this Part (rule).

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; amds. filed: June  
**Note:** 25, 1985; June 9, 1994; April 15, 1999 eff. May 5, 1999. Amended (a).

### § 38.3 Definitions.

(a) As used in this Part (rule), these terms have the definitions set forth below:

(1) "A<sub>1</sub>" means the maximum activity of special form radioactive material permitted in a Type A package. "A<sub>2</sub>" means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are either listed or may be derived in accordance with the procedure prescribed in Appendix A-12 of section 38.41 of this Part (rule).

(2) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

(3) "Accelerator-produced material" means any material made radioactive by a particle accelerator.

(4) "Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

(5) "Adult" means an individual 18 years, or more, of age. (6) "Agreement state" means any State with which the United States Nuclear Regulatory Commission or the United States Atomic Energy Commission has entered into an effective agreement under section 274b of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

(7) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dust, fumes, particulates, mists, vapors, or gases.

(8) "Airborne radioactivity" area means a room, enclosure, or area in which airborne radioactive materials exist in concentrations:

(i) in excess of the derived air concentrations (DACs) specified in Appendix A-13 of section 38.41 of this Part (rule); or

(ii) to such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

(9) "Annual limit on intake (ALI)" means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. The derived limit for a given radionuclide is the lesser of the following: the intake by reference man in a year that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent to any individual organ or tissue of 0.5 Sv (50 rem). ALI values for intake by ingestion and inhalation of selected radionuclides are given in Appendix A-13 of section 38.41 of this Part (rule).

(10) "As low as is reasonably achievable (ALARA)" means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these regulations as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of sources of radiation in the public interest

(11) "Background radiation" means radiation from cosmic sources, naturally occurring radioactive materials in the environment including radon (except as a decay product of regulated sources or special nuclear material), and global fallout as it exists in the environment from the testing of nuclear explosive devices. Background radiation does not include radiation from radioactive materials regulated by the department.

(12) "Becquerel (Bq)" means the SI unit of activity. One becquerel is equal to one disintegration or transformation per second ( $s^{-1}$ ).

(13) "Bioassay" means the determination of kinds, quantities or concentrations, and in some cases, the locations of radioactive material in the human body; whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these regulations, radiobioassay is an equivalent term.

(14) "Byproduct material" means:

(i) any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and

(ii) the tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute byproduct material within this definition.

(15) "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter, and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method used to determine calendar quarters for purposes of these regulations except at the beginning of a calendar year.

(16) "Calibration" means the determination of:

(i) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or

(ii) the strength of a source of radiation relative to a standard.

(17) "CFR" means Code of Federal Regulations.

(18) "Class" means a classification scheme for inhaled materials according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days; for Class W, Weeks, from 10 to 100 days; and for Class Y, Years, of greater than 100 days. For purposes of these regulations, "lung class" and "inhalation class" are equivalent terms.

(19) "Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

(20) "Commissioner" means the Commissioner of Labor of the State of New York.

(21) "Committed dose equivalent ( $H_{T,50}$ )" means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

(22) "Committed effective dose equivalent ( $H_{E,50}$ )" is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ( $H_{E,50} = \sum W_T H_{T,50}$ ).

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

(24) "Controlled area" means any area to which access is controlled for the purpose of protecting individuals from exposure to radiation and radioactive material, but shall not mean any area used as residential quarters. Controlled area as used in this Part is synonymous with restricted area.

(25) "Curie" means a unit of activity. One curie (Ci) is that quantity of radioactive material which disintegrates or decays at the rate of  $3.7 \times 10^{10}$  transformations per second.

(26) "Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy. The written declaration shall include an estimated date of conception or the estimated age of the embryo/fetus in days or weeks as of the date of declaration.

(27) "Decommission" means to remove (as an installation) safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of license.

(28) "Deep dose equivalent" ( $H_d$ ), which applies to external whole body exposure, means the dose equivalent at a tissue depth of one centimeter ( $1000 \text{ mg/cm}^2$ ).

(29) "Department" means the New York State Department of Labor and shall include its duly authorized representatives.

(30) "Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present.

(31) "Derived air concentration (DAC)" means the concentration of a given radionuclide in air which, if breathed by reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these regulations, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Appendix A-13 of section 38.41 of this Part (rule).

(32) "Derived air concentration-hour (DAC-hour)" means the product of the concentration of radioactive material in air (expressed as a fraction or multiple of the derived air concentration for each radionuclide) and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC-hours to represent 1 ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

(33) "Dose or radiation dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent.

(34) "Dose equivalent ( $H_T$ )" means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

(35) "Dosimetry processor" means an individual or organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

(36) "Effective dose equivalent ( $H_E$ )" means the sum of the products of the dose equivalent to each organ or tissue ( $H_T$ ) and the weighting factor ( $W_T$ ) applicable to each of the body organs or tissues that are irradiated ( $H_E = \sum W_T H_T$ ).

(37) "Embryo/fetus" means the developing human organism from conception until the time of birth.

(38) "Entrance or access point" means any location through which an individual could gain access to radiation areas or to radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

(39) "Exposure" means either:

(i) being exposed to ionizing radiation or to radioactive material; or

(ii) the quotient of  $dQ$  by  $dm$  where " $dQ$ " is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass " $dm$ " are completely stopped in air. The special unit of exposure is the roentgen (R). One roentgen is equal to  $2.58 \times 10^{-4}$  coulomb per kilogram of air.

(40) "External dose" means that portion of the dose equivalent received from any source of radiation outside the body.

(41) "Extremity" means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

(42) "Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter ( $300 \text{ mg/cm}^2$ ).

(43) "Gray (Gy)" means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule/kilogram. One gray is equal to 100 rad.

(44) "High radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

(45) "Human use" means the internal or external administration of radiation or radioactive material to human beings.

(46) "Individual" shall mean any human being.

(47) "Individual monitoring" means the assessment of:

(i) dose equivalent;

(a) by the use of individual monitoring devices; or

(ii) committed effective dose equivalent;

(a) by bioassay; or

(b) by determination of the time-weighted air concentrations to which an individual has been exposed; that is, DAC-hours.

(48) "Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these regulations, individual monitoring equipment and personnel monitoring equipment are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket dosimeters, and personal air sampling devices.

(49) "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

(50) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

(51) "License" means a radioactive material license issued by the commissioner in accordance with the regulations adopted by the commissioner. There are two types of licenses: general and specific. A general license means a license issued pursuant to the terms and conditions of section 38.5 of this Part (rule). General licenses are effective without the filing of an application with, or the issuance of a licensing document by, the commissioner. A specific license shall mean a license evidenced by a licensing document issued by the commissioner to a licensee. A specific license also means a similar license issued by the State Department of Health, the New York City Department of Health, the United States Nuclear Regulatory Commission or any agreement state. Unless otherwise specified, the type of license referred to in this Part will be a specific license.

(52) "Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the commissioner.

(53) "Licensee" means any person who is licensed by the commissioner in accordance with these regulations or one who possesses any radioactive material which is subject to the licensure requirements of this Part (rule).

(54) "Limits or dose limits" means the permissible upper bounds of radiation doses.

(55) "Lost or missing licensed material" means licensed material whose location is unknown. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

(56) "Member of the public" means any individual, except an individual who is performing assigned duties for the licensee or registrant involving exposure to sources of radiation.

(57) "Minor" means an individual less than 18 years of age.

(58) "Monitoring" means the measurement of radiation levels, radioactive material concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these regulations, radiation monitoring and radiation protection monitoring are equivalent terms.

(59) "NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.

(60) "Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these regulations, a deterministic effect is an equivalent term.

(61) "Nuclear Regulatory Commission (NRC)" means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

(62) "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include doses received: from background radiation, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the public.

(63) "Operator" means any person conducting the business or activities carried on within the radiation installation or having by law the administrative control of a radiation source whether as owner, lessee, contractor, or otherwise.

(64) "Package" means the packaging, together with its radioactive contents as presented for transport.

(65) "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium with energies usually in excess of one MeV.

(66) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, but shall not include Federal government agencies.

(67) "Personnel monitoring equipment" (see individual monitoring devices).

(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 materials and excluding activities incidental to decontamination or decommissioning.

(70) "Protective barrier" means a barrier of radiation absorbing material(s) used to attenuate the useful beam and/or stray radiation to the degree required to assure compliance with sections 38.18 and 38.19 of this Part (rule).

(71) "Public dose" means the dose received by a member of the public from exposure to sources of radiation regulated by this Part (rule). It does not include occupational dose, dose received from background radiation, dose received as a patient from medical practices, or dose from voluntary participation in medical research programs.

(72) "Quality factor (Q)" means the modifying factor, that is used to derive dose equivalent from absorbed dose.

(i) As used in these regulations, the quality factors for converting absorbed dose to dose equivalent are shown in [Table 1](#) of this paragraph.

(ii) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in [Table 1](#) of this paragraph; 0.01 Sv (1 rem) of neutron radiation of unknown energies may, for purposes of these regulations, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from [Table 2](#) of this paragraph to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

(73) Quarter (see calendar quarter).

(74) "Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg/gram or 0.01 joule/kilogram (0.01 gray). One millirad equals 0.001 rad.

(75) "Radiation" means alpha particles, beta particles, gamma rays, X-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these regulations, ionizing radiation is an equivalent term. Radiation, as used in these regulations, does not include non-ionizing radiation, such as radiowaves or microwaves, visible, infrared or ultraviolet light.

(76) "Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

(77) "Radiation equipment" means any equipment or device which can emit radiation by virtue of the application thereto of high voltage.

(78) "Radiation installation" means any place, facility or mobile unit where a radiation source is located or used.

(79) "Radiation safety officer" shall mean an individual who, under the authorization of the operator of a radiation installation, administers a radiation protection program in accordance with section 38.17 of this Part (rule) and who is qualified by training and experience in radiological health to evaluate the radiation hazards of such installation and administer such radiation protection program.

(80) "Radiation source" means any radioactive material or any radiation equipment.

(81) "Radioactive material" means any solid, liquid, or gas which emits radiation spontaneously.

(82) "Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

(83) "Reference" man means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used to standardize results of experiments and to relate biological insult to a common base.

(84) "Registrant" means any person who is registered with the commissioner or is legally obligated to register with the commissioner pursuant to these regulations.

(85) "Registration" means registration with the commissioner in accordance with these regulations.

(86) "Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).

(87) "Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive material.

(88) "Restricted area" means any area to which access is controlled for the purpose of protecting individuals from exposure to radiation and radioactive material, but shall not mean any area used as residential quarters. Restricted area as used in this Part (rule) is synonymous with controlled area.

(89) "Roentgen" means the special unit of exposure. One roentgen (R) equals  $2.58 \times 10^{-4}$  coulombs/kilogram of air (see exposure).

(90) "Sanitary sewerage" means a system of public sewers for carrying off waste and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

(91) "Scattered radiation" means radiation whose direction has been altered during passage through matter. (It may have been modified also by a decrease in energy.)

(92) "Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

(93) "Shallow dose equivalent" (Hs), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter ( $7\text{mg}/\text{cm}^2$ ) averaged over an area of one square centimeter.

(94) "SI" means an abbreviation of the International System of Units.

(95) "Sievert" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

(96) "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

(97) "Source" material means:

(i) uranium or thorium, or any combination thereof, in any physical or chemical form; or

(ii) ores that contain by weight one-twentieth of one percent (0.05 percent) or more of uranium, thorium, or any combination of uranium and thorium. Source material does not include special nuclear material.

(98) "Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

(99) "Special form radioactive material" means radioactive material which satisfies the following conditions:

(i) it is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(ii) the piece or capsule has at least one dimension not less than five millimeters (0.197 inch); and

(iii) it satisfies test requirements specified by the U.S. Nuclear Regulatory Commission (NRC) in 10 CFR 71.75 and 71.77, January 1, 1994;<sup>1</sup> except that special form radioactive material constructed prior to July 1, 1985 and meeting the requirements of 10 CFR 71 in effect on June 30, 1983 may continue to be used.

(100) "Special nuclear material" means:

(i) plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the U.S. Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

(ii) any material artificially enriched by any of the foregoing but does not include source material.

<sup>1</sup>**FOOTNOTE** - 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, NY or the New York State Department of State, 162 Washington Avenue, Albany, NY.

(101) "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: for each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

(102) "State" means the State of New York, unless the context of this Part (rule) clearly indicates that a different meaning is intended.

(103) "Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these regulations, probabilistic effect is an equivalent term.

(104) "Stray radiation" means the sum of leakage and scattered radiation.

(105) "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

(106) "These regulations" mean all parts of Industrial Code Rule 38 (12 NYCRR Part 38).

(107) "Total effective dose equivalent" (TEDE) means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

(108) "U.S. Department of Energy" means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the department exercises functions formerly vested in the U.S. Atomic Energy Commission, its chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the administrator thereof pursuant to section 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, 42 U.S.C. 5814, effective January 19, 1975) and transferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977).

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

(110) "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

(111) "Use as used in radioactive materials licenses" means to employ or apply radioactive materials for the licensed purpose. It shall include instruction of, and responsibility for, technical and support staff members. It does not include training others in the techniques of use of radioactive materials for the purpose of qualifying for licensure.

(112) "Useful beam" means the radiation which passes through the source or tube-housing port and the aperture of the collimating device when the exposure switch or timer is activated.

(113) "Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in one hour at 1 meter from a source of radiation or from any surface that the radiation penetrates.<sup>2</sup>

(114) "Waste handling licensees" means persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive wastes.

(115) "Week" means seven consecutive days starting on Sunday. dispose of radioactive wastes.

(116) "Weighting factor  $W_T$  for an organ or tissue (T)" means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of  $W_T$  are:

ORGAN DOSE WEIGHTING FACTORS

Organ or tissue	$W_T$
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30 <sup>a</sup>
Whole body	1.00 <sup>b</sup>

(a) 0.30 results from 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

<sup>2</sup>**FOOTNOTE** - At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.

(b) For purposes of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor,  $W_T = 1.0$ , has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

(117) "Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

(118) "Worker" means an individual engaged in work under a license or registration issued by the commissioner and controlled by a licensee or registrant, but does not include the licensee or registrant.

(119) "Working level" (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of  $1.3 \times 10^5$  MeV of potential alpha particle energy. The short-lived daughters of radon-222 are: polonium-218, lead-214, bismuth-214, and polonium-214. The short-lived daughters of radon-220 are: polonium-216, lead-212, bismuth-212, and polonium-212.

(120) "Working level month" (WLM) means an exposure to 1 working level for 170 hours (2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month).

(121) "Year" means the period of time beginning in January used to determine compliance with the provisions of these regulations. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

**Historical Note:** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; amds. filed: June 25, 1985; March 15, 1993; repealed, new filed June 9, 1994 eff. June 29, 1994; amd. filed April 15, 1999 eff. May 5, 1999

**§ 38.2 Variations.**

The commissioner may grant variations from this Part (rule) pursuant to the provisions of section 30 of the Labor Law and section 483 of the General Business Law.

**Historical** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; amd. filed June 9,  
**Note:** 1994 eff. June 29, 1994.

### **§ 38.1 Applicability.**

a) Except as herein provided, this Part (rule) applies throughout the State to every person who, in any industry, trade, occupation or process in the State, transfers, receives, possesses or uses any radiation source while such source is free from and not subject to the regulatory powers and jurisdiction of the State Department of Health or the New York City Department of Health.

(b) This Part (rule) also applies to every person who, in any industry, trade, occupation or process, engages in the installation, testing or servicing of radiation equipment that may result in exposure to ionizing radiation.

(c) This Part (rule) does not apply to any common or contract carrier operating within this State to the extent that such carrier is subject to regulation as provided for by law by the United States Department of Transportation or other agencies of the United States, or agencies of the State of New York, other than the Department of Labor, having jurisdiction.

(d) This Part (rule) does not apply to any person to the extent that such person obtains, possesses, or uses such items as are enumerated in Table 1 of section 38.41 of this Part (rule).

**Historical Note:** Sec. amd. filed June 10, 1971; repealed, new filed July 6, 1978; amd. filed June 25, 1985; repealed, new filed June 9, 1994 eff. June 29, 1994.

**§ 38.42**

**Historical** Sec. repealed, filed June 10, 1971, eff. Sept. 1, 1971.

**Note:**